BNCI Horizon 2020

The Future of Brain/Neural Computer Interaction: Horizon 2020

Appendix D Use Cases and Focus Groups

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This appendix and the corresponding main document can be downloaded from
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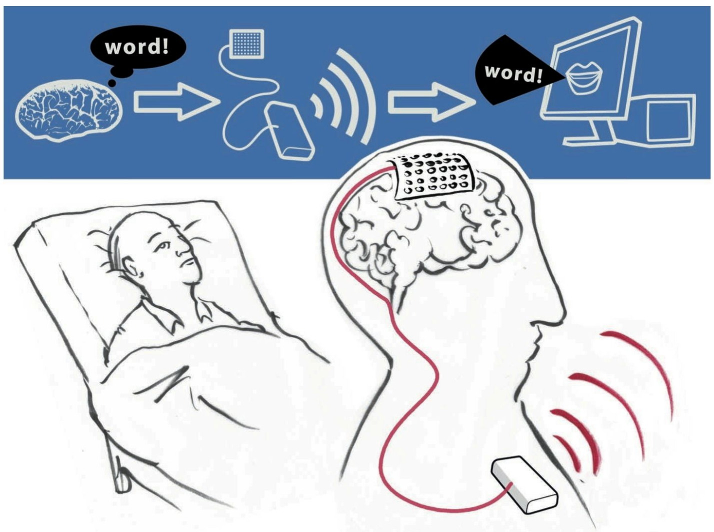
D Use Cases and Focus Groups

D.1 Use Cases

D.1.1 Replace

D.1.1.1 Unlocking the locked-in



Eric is a 28-year old teacher who suffered from a brainstem stroke. One year after the event, and despite intensive rehabilitation therapy, he remains unable to move or speak. The only muscles that he can control are those of the eyes. He uses eye movements to answer simple yes/no questions, but he cannot communicate for longer periods because he gets tired quickly. Eric has tried to use an eye tracker for more advanced communication, but his eye gaze is too unstable to make this work. Also, a brain-computer interface (BCI) speller based on brainwave recordings from his scalp allows him only limited and slow communication.

The rehabilitation technician refers Eric and his caregivers to a neurosurgeon to discuss the option of implanting a BCI system for communication. This device is capable to decode inner speech and wirelessly transmit it to a speech computer. Eric and his caregivers realize that the surgical procedure could be Eric's only chance to obtain autonomy and ability to express his wishes, thoughts, and emotions. Therefore, Eric decides to undergo the implantation. He first receives a functional MRI scan to precisely locate the brain areas that are activated when Eric produces internal speech. Eric is then brought to the operating room for implantation of the BCI device. The whole device has more than 100 tiny electrodes and electronics integrated within one thin plastic sheet.

After recovery, Eric returns to the rehabilitation center, where he is trained to use his inner speech brain signals. After a few days, Eric is able to express simple words via a speech computer. After a few weeks, he is able to generate complete sentences and to express his opinion and emotions.

Primary users	Patients
Secondary users	Doctors/surgeons, caregivers
Tertiary users	Health care system, health insurance companies
Target group size	Very small
Market size	Many causes possible, most common causes of severe paralysis with only very limited communication: ● ALS: prevalence is ~4-6 per 100,000 people, not all become locked-in (or functioning at that level) ● Subgroup of brain stem stroke survivors (classical locked-in): prevalence unknown, possibly around 1-2 per million
Current treatment/options	● Eye tracker ● Various EMG-based switches or joysticks (chin, head, mouth, finger etc.) ● pH strip (yes/no=sweet/sour; GSR) ● EEG/NIRS-based BCIs
Cost of current treatment/options	● Eye tracker: 5,000-17,000 USD ● Various switches and joysticks: varies (starting at 2,000 USD) ● EEG/NIRS-based BCIs: 5,000-50,000 USD
Advantages/disadvantages of current treatment/options	Eye tracker: ADVANTAGES: - No surgery - Works quite well (when the above issues are not present) - 2D cursor movement + click possible DISADVANTAGES - Problems when people have glasses - Problems when people have unstable eye gaze - Not usable for completely locked-in patients - Can be tiring - May not be available at night Various switches and joysticks: ADVANTAGES: - Works quite well if the used muscle can be controlled reliably - No surgery DISADVANTAGES: - May require careful positioning of the device (and very regular adjustments by caretaker) - May not be available at night - Not usable for completely locked-in patients EEG/NIRS-based BNCI systems: ADVANTAGES: - no surgery - works quite well (when the above issues are not present) - 2D cursor movement + click possible DISADVANTAGES: - third person required to setup the system - unreliable - cannot be used 24/7 - can be tiring - some patients cannot use this device (BCI illiterates) - slow
Who pays?	- Health Care system - Private health insurance companies - The patient
Expected advantages/disadvantages of implantable BCIs compared to current treatment/options	ADVANTAGES: available 24/7 - fast communication - usable for completely locked-in patients as well – cosmetically more acceptable than other solutions DISADVANTAGES:

	- for implantable BCI: surgery required entails some surgical risks – these risks vary depending on the technique used (epidural, subdural, intracortical) – upgrading of implanted devices requires another surgery
From a user perspective, what needs to be resolved before the implantable BCI solution can be applied?	- Proof of efficacy in the home environment - Proof of safety (surgery, but also use in the home environment)
Ethical issues	- Price (issue of justice) - Privacy (e.g. of thoughts) - Agency, safety and responsibility in the case of unwanted actions/sentences - Risks related to implant
BCI technologies needed	- Very high resolution ECoG grids or other implantable sensor systems + approval for long-term implant - Advanced signal processing techniques to decode internal speech - Demonstration of the value of fMRI for pre-localization of implantation site (with this level of detail) - Fully implantable amplifier able to amplify many channels at a decent sampling rate + approval for long-term implantation
Competing new technologies	Implantable BMI can be seen as disruptive technology once the disadvantages, mainly surgical risks and reliability, are resolved as no other technology can achieve this bandwidth (communication speed). Other technologies, e.g. autonomous systems using cameras and superficial bio-sensors may achieve better results than the currently available solutions (eye-trackers, pH-systems etc.), but it is unlikely that they can compete with implantable BMI.
Expected advantages/disadvantages of BCIs compared to competing new technologies	ADVANTAGES: Available 24/7 - fast communication and interaction with the environment -potentially a very natural, intuitive, way of communication – cosmetically more acceptable than other solutions DISADVANTAGES: - for implantable BCI: surgery required entails some surgical risks – these risks vary depending on the technique used (epidural, subdural, intracortical) – upgrading of implanted devices requires another surgery
Fields with shared benefits (synergies)	- neuro/brain stimulation - electronics (many-channel implantable amplifiers)
What is required to make this BCI solution commercially viable?	- medical device approval for ECoG or other implantable BNCI systems - changed attitude towards implantable technologies
Incentive for industry, why would industry be interested?	- limited value for a large number of stakeholders, but may be still useful for a small number of companies, if they get the whole market share - High price will be an incentive (market value instead of market size) - increase of quality of life of target end users
Time to market	Midterm (7-10 years)
Major milestones for product success	- Device approval - Funding for each patient

Recommendations	- Support device approval and investments toward commercialization of implantable BNCI solutions in the EU

D.1.1.2 BCI-controlled robot assistant

Bruce Shelly is one of the top managers in the world. He owns five oil reserves, one in each continent. He has more than 10,000 employees all around the world. One year ago, Bruce had a car accident and since then, it has been very difficult for him to move his legs. Weeks of therapies helped him to regain partial control of his legs, which allows him to walk autonomously for a few hours a day.

During his recovery, the leadership of his companies was given to his oldest son Michael. Despite Michael's efforts to emulate his father entrepreneur skills, the oil reserves underwent a dramatic economic crisis. Bruce decided that the only way to be directly involved in his business again despite his motor disabilities was to buy a BCI-controlled robot assistance system. He equipped all offices of his companies with a steerable robot that translates Bruce's intentions into corresponding movements on site. The headset equipped with EEG electrodes has a virtual reality glass to allow Bruce to see and interact with the environment around him. For example, if Bruce turns his head, the robot does the same. Optionally, he can also wear a bodysuit, giving him tactile touch feedback. The robot has a small circular mobile platform equipped with three wheels and obstacle sensors. At the beginning, the mental effort to control the robot was huge, and the helmet on Bruce's head to measure his intentions was uncomfortable. But after a few weeks, he got the hang of it - and the control became natural and effortless. Bruce realized that the BCI-controlled robot assistant gave him much more freedom than he had before: he could be anywhere in the world at any time he wanted. Remarkably, Bruce's trades are now prolific and he is still one of the richest managers worldwide.

Primary users	Healthy people (i.e. employers and employees)
Secondary users	Industry, Family, Caregivers
Tertiary users	Headquarters, Health Care System
Target group size	> 10000
Market size	Small
Current treatment/options	1. Telepresence robots manually (i.e. joysticks, keyboards, mouse, touchpads) and/or voice controlled. 2. Video conferencing softwares.
Cost of current treatment/options	200 € - 20,000 € examples: http://nextbigfuture.com/2013/01/telepresence-robots-from-350-to-16000.html
Advantages/disadvantages of current treatment/options	(+) joystick- or keyboard-based remote control (+) social interaction between humans beings

Who pays?	Primary, secondary and tertiary users
Expected advantages/disadvantages of BCIs compared to current treatment/options	(+) Multi-tasking (+) Embodiment (-) Temporal lag
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Implementation of user-friendly, reliable and long-lasting BCI components.
Ethical issues	1. Loss of human interaction 2. Compromised privacy 3. legal issues? (e.g. in case of accidents who is responsible?)
BCI technologies needed	1. Wireless and dry EEG electrodes 2. Noise reduction 3. Artifact removal
Competing new technologies	1. Voice recognition 2. Face recognition 3. Motion capture
Expected advantages/disadvantages of BCIs compared to competing new technologies	(+) The robot assistant can sense the current mental state (mood, workload, stress level) and adapt it's behaviour (+) emergency situation could be recognized (+) via error potentials wrong made decision could be detected (+) In the industry the user could give control command to the robot without being interrupted (+) With invasive BCIs sensory information could be feed into the user's brain (-) variable communication delays (-) end-users need to be able to apply the systems independently
Fields with shared benefits (synergies)	1. Robotics 2. Information technology
What is required to make this BCI solution commercially viable?	Improved BCI Hardware: dry, comfortable electrodes, miniaturized wireless amplifier, customisation, servicing, personalisation. Improved robotics. home-support.
Incentive for industry, why would industry be interested?	1. To decrease travelling costs of employers/employees 2. To allow employers/employees to access any site worldwide every time is needed; 3. To increase communication speed among collaborators; 4. To increase productivity of employers/employees
Time to market	Mid term: 5-10 years
Major milestones for product success	1. Improve BCI hardware for comfort and usability 2. Prove the additional benefits of BCI technology to existing robotics. 3. Acceptance of robotic assistance and BCI technology in everyday life 4. Adoption by the users and healthcare system.

Recommendations	1. Strengthen collaboration with the Robotics field. 2. Invest in development of lightweight comfortable and reliable BCI hardware.

D.1.1.3 Bionic hand with sensory feedback

Andy is a 39-year old tattoo artist. Due to a motorcycle crash two years ago, he has lost his right hand. During the first months after the crash, Andy was depressed because he was afraid he could never perform his job again. After having recovered from the injuries, his surgeon mentioned the possibility to obtain a brain-controlled bionic hand that also provides sensory feedback to the brain.

Although Andy was quite scared of brain surgery, he chose to have the implant. He received two multi-electrode arrays: one in the primary motor area of the hand, and one in the primary sensory area of the hand. Small wires connect the electrodes to an amplifier/stimulation device that was implanted in the chest area. Andy also received a fancy bionic hand that communicates wirelessly with the implanted device. It took him some months to learn how to control the bionic hand correctly, but he is very proficient now. Andy has learned that just attempting to make the same movements that he would make with an intact hand can produce the same movements of the bionic hand. In addition, the bionic hand contains sensors that send information to the device in his chest, and from there to the electrodes on his brain surface. Each time the sensors of the bionic hand are activated, small currents provide Andy with a sense of touch.

Last week, Andy has created his first tattoo using his bionic hand. It was a simple picture, but he is confident that after more practice, he will be able to get back to his old skill level.

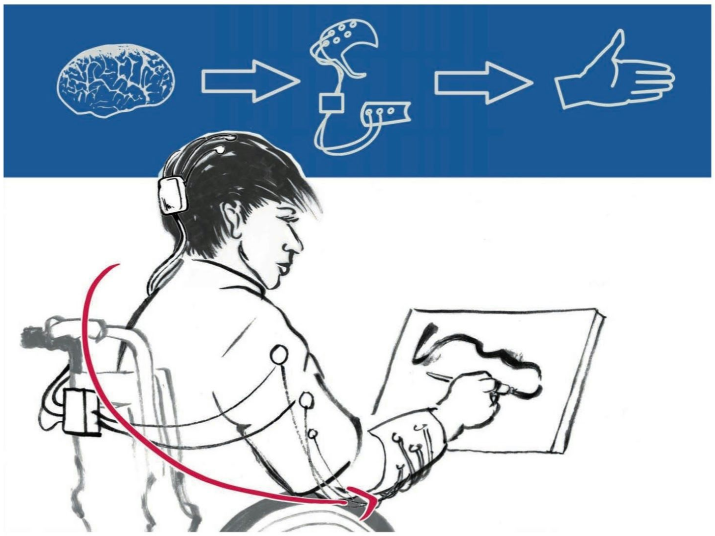
Primary users	Patients
Secondary users	Doctors/surgeon, caregivers
Tertiary users	Health Care system, health insurance companies
Target group size	Small
Market size	- 10 million amputees worldwide, 3 million of which are arm amputees, 2.4 million of which live in developing countries. Of all arm amputations, 5% is hand amputation, and 59% below elbow. - About 50,000 amputations per year in the US, about 15-20% is upper limb
Current treatment/options	- occupational therapy for e.g. basic living tasks and change of dominance - body-powered prosthesis (cable-controlled via other muscles in the body) - externally powered prosthesis: servo, switch (controlled by small switches that are manipulated by e.g. remaining digits or bony prominences) or myoelectric (controlled by contraction of remaining muscles at amputation site). Myoelectric prosthesis are available with independent control over 4-5 digits. BCI-controlled prosthesis would fall under externally powered prosthesis as well.

Cost of current treatment/options	Very much depends on type of prosthesis chosen.
Advantages/disadvantages of current treatment/options	- body-powered prosthesis: ADVANTAGES: sensory feedback through harness system, durable, inexpensive, light weight, safe because no surgery DISADVANTAGES: have only possibility to control 1 joint at a time, limited range of motion, limited prehensile strength, look unnatural and less cosmetically appealing - externally powered: ADVANTAGES: - safe - control over more degrees of freedom than body-powered - EMG-based systems are relatively cheap, and the recording technique is mature - EEG-based systems are relatively safe DISADVANTAGES: - early generations based on switches are slow and cumbersome - EMG-based systems may be unreliable, electrodes difficult to position and replace in exact the same location, voluntary muscle gets different function, difficult to learn - EEG-based systems require intensive training
Who pays?	- Healthcare system - Private health insurance companies - The patient
Expected advantages/disadvantages of BCIs compared to current treatment/options	ADVANTAGES: All degrees of freedom that a real hand has, can be controlled by the BCI system. The control accuracy will be improved through a natural learning process. The control accuracy will be better. No "workaround" through another nervous pathway is needed. The BCI controlled bionic hand would provide the most intuitive replacement of a lost hand. Very rich signal. Direct feedback of sensory information. DISADVANTAGES: The need of an invasive brain surgery. The wireless amplifier unit would have a high power consumption for running the whole day. This would demand a recharging quite often(?). The total costs would be higher. Neural recording with micro-arrays is susceptible to external movement, which may result in signal loss. Tissue reaction to the electrodes also may lead to signal loss.
From a user perspective, what needs to be resolved before the BCI solution can be applied?	- Proof of principle in humans - Proof of efficacy in the home environment - Proof of safety (surgery, but also use in the home environment)
Ethical issues	- Security issues: one could hack the wireless data transmission. - Possibility to extend life past its natural term? Theoretically everything except the brain could be replaced?? - "Cyborg" issue. New limbs could be more powerful that natural limbs. - Price (issue of justice) - Agency, safety and responsibility in the case of unwanted actions - Risks related to implant
BCI technologies needed	- Implants are needed that provide good signal quality over several years. - Completely implantable many-channel BCI technology with low power consumption. - Research on how to optimally provide sensory feedback (force, vibration, fine point contact, temperature, joint angle, velocity, torque) to the sensory cortex - Decoding signals for high-degrees of freedom control over multiple joints

Competing new technologies	- targeted muscle reinnervation surgery to optimize possibilities for myoelectric control - non-invasive neural control of bionic hand - for those with paralyzed, but not amputated, limbs FES with intramuscular electrodes is a recent development
Expected advantages/disadvantages of BCIs compared to competing new technologies	ADVANTAGES: All degrees of freedom that a real hand has, can be controlled by the BCI system. The control accuracy will be improved through a natural learning process. The control accuracy will be better. No "workaround" through another nervous pathway is needed. The BCI controlled bionic hand would provide the most intuitive replacement of a lost hand. Very rich signal. Direct feedback of sensory information. DISADVANTAGES: The need of an invasive brain surgery. The wireless amplifier unit would have a high power consumption for running the whole day. This would demand a recharging quite often(?). The total costs would be higher. Neural recording with micro-arrays is susceptible to external movement, which may result in signal loss. Tissue reaction to the electrodes also may lead to signal loss.
Fields with shared benefits (synergies)	robotics, material science, biomechanics
What is required to make this BCI solution commercially viable?	For the moment it is an research option
Incentive for industry, why would industry be interested?	Limited value for a large number of stakeholders Still useful for a small number of companies, if they get the whole market share
Time to market	Long-term (> 10 years)
Major milestones for product success	- improved context awareness - improved flexibility - goal-oriented protocols (thinking about the end objective and then everything else is automatically done) (Wolpaw, 2007)
Recommendations	- Improving BCI robustness - Pursue invasive directions

D.1.2 Restore

D.1.2.1 BCI-controlled neuroprosthesis



Anna is a 39 year old construction engineer. Two years ago, she was working at a construction site and a wooden beam hit her directly on her neck. An air ambulance helicopter quickly brought her to a trauma center, where doctors diagnosed a complete spinal cord injury at the sixth vertebra. One year later, Anna is discharged from the rehabilitation center and returns back home. She is unable to move her legs, and she has a complete loss of hand function necessary to grasp objects.

During one of her periodic rehab stays, Anna meets Katie, a rehabilitation therapist. She works in the rehab center to apply neuroprostheses. Katie is pretty sure that she can help Anna regain hand movements well enough for her to get back to work. As a first step, she runs several tests to assess Anna’s muscle activity, arm movement, and brain patterns. “The brain patterns will be used for you to grasp and manipulate things”, Katie explains.

A couple of weeks later, Katie is finished with making the neuroprosthesis. Anna also gets a very thin and cool-looking frame with self-connecting sensors, which will be recording her brain patterns. Katie teaches her how to generate very natural grasps by specific thoughts. Anna’s thoughts trigger electrical pulses in the prostheses, which are applied to her hand muscles. First, Anna starts with very crude movements, and she gets feedback about the process directly on her tablet computer. She has to think of moving her hand to produce unique brain patterns that can be detected by the neuroprosthesis. The training program rapidly adapts itself to Anna’s progress, and includes finer movements as she gets better in controlling her device.

Half a year later, Anna uses her neuroprosthesis on a daily basis. She is able to grasp and hold simple objects, and she is back in her old job as a construction engineer. In her leisure time, she even started to paint.

Primary users	Patients with spinal cord injury, paraplegics, quadriplegics, brain stem stroke
Secondary users	Family, caregivers
Tertiary users	Therapists, medical doctors
Target group size	23.000-28.750 in Europe
Market size	Small
Current treatment/options	Full-time caregiving; neuroprosthesis + shoulder joystick
Cost of current treatment/options	Full-time caregiving: 8,000€/month, neuroprosthesis: 2,000-10,000€, shoulder joystick: 2,000-5,000€.
Advantages/disadvantages of current treatment/options	Full-time caregiving: Disadvantages: costs of caregiving and the lack of autonomy, limited degree of freedoms Advantages: safety, social aspects of not being „alone“ Neuroprosthesis: Disadvantages: needs to be adapted to each individual user, unreliable, often requires 3rd person to mount and dismount Advantage: increased autonomy and ability to participate in daily life activities
Who pays?	Insurance, patient, family, charity
Expected advantages/disadvantages of BCIs compared to current treatment/options	gaining back some autonomy; intuitive brain control; savings of 8.47 Mio. EUR per year from new SCI end users (177.8 Mio. EUR per year from population): FES has also therapeutic usage
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Robust and reliable decoding of biosignals; easy application/setup, intuitive control, easy to mount, easy to switch on and off
Ethical issues	Agency, responsibility for unwanted actions
BCI technologies needed	Robust and reliable decoding of biosignals; dry or solid-gel electrodes with good SNR for long-term use
Competing new technologies	Autonomous systems using cameras and non-brain biosignals, e.g. EMG, EOG
Expected advantages/disadvantages of BCIs compared to competing new technologies	Advantage: Intuitive use; can potentially restore functions of both arms Disadvantage: Possibly expensive, needs medical device approval
Fields with shared benefits (synergies)	IT technologies, neuro/brain stimulation, electronics
What is required to make this BCI solution commercially viable?	Either inexpensive products or insurance coverage

Incentive for industry, why would industry be interested?	cutting-edge technology with high visibility, high social value
Time to market	5-10 years
Major milestones for product success	demonstration that restoration of normal function can be achieved with such device over a longer period of time (e.g. whole day demonstration), device approval, wide-spread standard use in rehabilitation hospitals
Recommendations	- Support device approval and investments toward commercialization of BNCI solutions in the EU

D.1.2.2 Cochlear implant adjustment

Alfred was born with severe hearing loss. He was quite lucky, because his parents and the doctors detected his hearing loss very early. The doctors suggested a new technology to them: a cochlear implant. A cochlear implant is a surgically implanted electronic device that restores the ability to hear. Alfred received his first cochlear implant at the age of 9 months. Due to the fact that the technology is very well tested and highly robust, his implant still works 25 years later. However, one problem has always bothered Alfred: it is very difficult to fine-tune the settings of the device. For example, sometimes he hears just low frequency tones, sometimes just high, or certain frequency bands are louder than others. Thus, the hearing quality is highly variable within weeks, days, and sometimes even within hours.

After the latest update of the implant, it has a novel feature. The settings of the implant are automatically adjusted to the Alfred's needs by a brain-computer interface (BCI). An electrode on the external part of the implant continuously monitors Alfred's brain activity, and thereby the implant is dynamically fine-tuned. After receiving the upgrade of the cochlear implant, Alfred realized that there is no need for manual fine-tuning any more. He enjoys an improved hearing quality, which is stable and reliable over years.

Primary users	Persons who is profoundly deaf or severely hard of hearing
Secondary users	Audiologists
Tertiary users	Hospitals, Researchers
Target group size	Large; approx. 600.000 p/year
Market size	Very large. The WHO suggest that in 2012 approximately 360 million people in the world suffered from disabilities pertaining to hearing loss In 2010 approximately 70,000 individuals—over half of whom were children—had received cochlear implants in the United States. More than 219,000 individuals have received cochlear implants worldwide (http://www.asha.org/public/hearing/Cochlear-Implant-Frequently-Asked-Questions/)
Current treatment/options	Currently, the CI have to be recalibrated on a regular basis in order to maintain an acceptable hearing quality.

Cost of current treatment/options	Including the post-operative aural rehabilitation process, costs exceed $40,000. However, cochlear implantation consistently ranks among the most cost-effective medical procedures ever reported, according to research completed by the Johns Hopkins University and the University of California-San Diego. These studies indicate that cochlear implantation can result in a net savings of more than $53,000 (http://www.asha.org/public/hearing/Cochlear-Implant-Frequently-Asked-Questions/)
Advantages/disadvantages of current treatment/options	Current CI systems need regular manual adjustment (at least yearly) in order to maintain an acceptable shearing quality. BCI-based CI systems with an self-calibration could increase the hearing quality and enable less frequent manual adjustments.
Who pays?	Public healthcare system (eg. Spain, UK, Germany) Private health insurance companies ot the user (eg. US) As CIs have been proven to be a very cost-effective treatment, the health insurance coverage for cochlear implant services has improved greatly in recent years, with the majority of commercial health plans and managed care organizations now providing some level of benefits for the procedure and related services, including programming and aural rehabilitation.
Expected advantages/disadvantages of BCIs compared to current treatment/options	
From a user perspective, what needs to be resolved before the BCI solution can be applied?	
Ethical issues	- Due to its invasiveness, the implantation of CI are generally subject to ethical considerations - Data privacy should be maintained for any type of CI
BCI technologies needed	
Competing new technologies	There is no competing technology that directly assessed the brain activity. However, future CIs could also be adjustable through other wireless control channels, which are operated in a manual or automated manner.
Expected advantages/disadvantages of BCIs compared to competing new technologies	
Fields with shared benefits (synergies)	(implantable) electrodes

What is required to make this BCI solution commercially viable?	Improved R&D of BCI combined with cochlear implant
Incentive for industry, why would industry be interested?	the large market size is an incentive for industry
Time to market	5-15 years (novel medical products require extensive clinical testing)
Major milestones for product success	(1) validation of BCI technology that can facilitate cochlear implants (2) improved BCIs sensors (3) integration of BCI sensors with other hardware
Recommendations	Invest directly in invasiveness technologies in the EU

D.1.2.3 Spinal cord stimulation for reach and grasp

Paula is a 24-year old woman who sustained a spinal cord injury due to a diving accident, which left her paralyzed from the neck. She is perfectly able to speak, and she controls a joystick with her mouth to steer her wheelchair and control her computer. She is very unhappy with this level of functioning, and with the fact that she needs to do everything with her mouth. She feels very dependent from others and has a strong desire to regain some level of arm and hand function to restore the capacity to perform other activities of daily living. Then, she could control her wheelchair and computer with her hand, and she could also eat by herself, without someone feeding her.

Paula's doctor tells her about an implantable BCI system that would allow her to control her own arm and hand muscles. Paula is immediately very interested in this option and decides to go for it. During surgery, a 96-channel electrode array is implanted in the primary cortex of the hand and arm area. The array is connected to an amplifier/stimulator, which is implanted in the chest area. From this device, fine wires continue to the spinal cord, where they are connected to the relevant nerves controlling hand and arm function.

After recovery from surgery, Paula follows a training program that allows her to learn to control her own arm for reach and grasp functions. She only has to attempt making the movement she desires, and then her brain activity patterns are translated into an electrical stimulation sequence for the spinal cord nerves, producing movement of her arm and hand. A few weeks later, Paula returns home and is very happy with her increased level of independence.

Primary users	Users with motor disabilities (e.g. individuals with SCI)
Secondary users	Physiotherapists, medical doctors, clinicians in general
Tertiary users	Managers, Health Care System
Target group size	Reasonably large (Worldwide, over 130,000 people sustain SCI, half of them remain affecting upper limbs)
Market size	Same, although not all of them could benefit from a solution, mainly because have other more important motor problems (i.e. breathing)

Current treatment/options	These patients typically receive rehab to maximize remaining motor capabilities (specially in incomplete injuries). Then, some can function with FES systems and others undergo tendon transposition surgeries to regain some functions. Some received in the past neuroprostheses (e.g. Freehand). These were discontinued due to lack of market interest.
Cost of current treatment/options	multichannel FES systems are expensive (over a thousand of euros), when they are neuroprosthesis that cost can be multiplied by 10 or more
Advantages/disadvantages of current treatment/options	Usability. Not permanent
Who pays?	Depends on the country. Mainly the patient.
Expected advantages/disadvantages of BCIs compared to current treatment/options	More natural control
From a user perspective, what needs to be resolved before the BCI solution can be applied?	There have been some attempts to use BCI to control the FES systems for reach and grasps. Aspects such as reliability and usability need to be improved
Ethical issues	Price (if it's too expensive to be a global solution)
BCI technologies needed	Very high accuracy to distinguish between different hand movements
Competing new technologies	Robotic arms or exoskeletons
Expected advantages/disadvantages of BCIs compared to competing new technologies	Control appears to be much more natural when is brain initiated.
Fields with shared benefits (synergies)	Rehabilitation, assistive technology for other pathologies such as Parkinson's disease
What is required to make this BCI solution commercially viable?	Research in better algorithms to detect brain patterns that can be converted into complex electrical stimulation sequences that activate UL muscles
Incentive for industry, why would industry be interested?	Although it is not a massive market, if the solution is effective, can be adopted to a larger number of end-users.
Time to market	Long-term >10 years
Major milestones for product success	Even if BCI is used in combination with FES, or with any other technology (e.g. robots). The use of BCI to restore grasp and reach functions.
Recommendations	

D.1.3 Improve

D.1.3.1 Hybrid BCI-driven FES for rehabilitation

Maria is a 57-year-old engineer from Rome. Recently, she had a stroke in the right side of her brain. Three months after the event, she is able to walk with a cane, but she has severe deficits in the left arm and hand that make it impossible to continue her work. As part of the standard rehabilitation program, Maria receives a home BCI rehabilitator. The system consists of a sleek headset with EEG sensors and a sleeve for her left arm. Some of the sensors on the inside of the sleeve record muscular activity. Other electrodes can apply electrical pulses to arm muscles. The system is fully automatic and works as follows: When Maria attempts to open her hand, both the brain and the arm signals are recorded and decoded. Only correct movement signals are then rewarded with electrical stimulation of the arm to support the movement. This leads to a closed-loop training mechanism and, after enough practise, to better control over the hand. Maria enjoys the training program, because it consists of specially designed computer games that make training time fly by. Sharing performance with other users through the web interface increases the motivation even further. When necessary, the system can be remotely adjusted by a therapist during a video call.
Many patients have already benefitted from this system, and many patients (including Maria) use it frequently to sustain their recovered hand or leg mobility. After three months of intensive training, Maria is back at work.

Primary users	Patients: post-stroke (subacute phase, chronic); (TBI; Brain tumor)
Secondary users	Family, caregivers
Tertiary users	Medical Doctors, therapists, health system, insurance companies

Target group size	Worldwide, 15 million people suffer a stroke each year; one-third die and one-third are left permanently disabled (WHO).In Europe and other developed countries the number of stroke events is likely increasing (from 1.1 million per year in 2000 to more than 1.5 million per year in 2025) because of the aging population (Truelsen et al., 2006). 70% of stroke survivors has deficits in arm movement and 40% is unable to use one arm in the long term (www.stroke.org)
Market size	Large aprox. 1 million upper limb rehabs due to stroke per year in 2025 (increasing nr. stroke patients (incidence) due to aging population).
Current treatment/options	Guidelines for rehabilitation (European Stroke Organization) mention: FES/robotic assisted training (eg. Amadeo System (Tyromotion), mechatronic rehabilitation device); aerobic training in general; Constraint-Induced Movement Therapy; Botulinum toxin for focal treatment of spasticity.
Cost of current treatment/options	Current cost of mechatronic rehabilitation devices for upper limb rehab (entire cost of clinical device, no therapist included): 1. MT Manus: 150k€ (aprox), 2. ReoGo: 60-70k€, 3. Amadeo: 40k€
Advantages/disadvantages of current treatment/options	Advantages: high acceptability by the operators and patients, non-invasive. Proven efficacy (CIMT, aerobic training, botulinum toxin...). Disadvantages: limited applicability to severely affected patients, who determine the highest social and economic burden. Experienced operator is needed. No direct control on patients' adherence to treatment and participation (bottom-up approach).
Who pays?	Public healthcare system (eg. Spain, UK, Germany, Austria, Italy); Private health insurance companies (eg. US vs. EU); The patient (eg. US)

Expected advantages/disadvantages of BCIs compared to current treatment/options	Advantages: BCI targets the brain, thus it provides a direct insight of brain activity (top-down approach). Sensorimotor integration (BCI as a support for this) is considered a valuable strategy in the scientific/medical environment. The fully automated system leads to reduced costs for the health system (shorter admissions, less outpatient therapists, less burden for caregivers). [Focus Group: BCI targets the brain, thus it provides a direct insight of brain activity (top-down approach). Therapist can monitor cortical activity during rehab maximizing conventional therapy results. Support to home rehabilitation. The fully automated system leads to reduced costs for the health system. Patients' motivation.] Disadvantages: rejection of the device by patients (alienation), usability issues? Safety issues? Side effects (maladaptive plasticity,...) [Focus Group: lack of human contact, ensure the therapy continuity, need for standardization of rehabilitation protocols]
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Proof of safety; Proof of efficacy. [From Focus Group: safety, reduce the cost, user-friendly devices, effectiveness, reduce size and impact on daily life. Previous validation in hospital setting. Need for standardization of rehabilitation protocols]
Ethical issues	Lack of a clear understanding of what BCI can cause in the brain in terms of plasticity and reorganization (common to all new neuromodulation strategies); patients alienation. [From Focus Group: patients alienation, proof of safety, bad plasticity, learning non-use. The technology should be available for everyone needing it (avoid social inequality). Ensure therapy continuity. Communication with patients (avoid unrealistic expectations) and communication with policy makers, this system cannot replace therapists' work, but support it]

BCI technologies needed	EEG-based SMR BCI and EMG classifier connected to FES system. 1) Hardware: EEG based on dry electrodes (Shih et al.,2012); Active electrodes (Brunner et al., 2011); Improve practicality: easy to setup, function for many hours without maintenance, work in all environments (Shih et al., 2012). 2) Data processing: Identification of optimal EEG and EMG signal features associated with movement intention (including those associated with 'unwanted' activation of flexors) (see fBNCI project, Grosse-Wentrup et al., 2011); Optimize feedback accuracy, delay and modality to boost effects of neural plasticity (Grosse-Wentrup et al., 2011); General EEG issues / BCI issues: increase information bit rate, improve reliability. 3) Other: Optimization of training paradigms (related to Silvoni et al., 2011); Integration of procedure into teams and approaches involved in stroke rehabilitation (Dimyan and Cohen, 2011); Definition of valuable functional outcome measures (Dimyan and Cohen, 2011); Large and long term clinical trials to: a) Establish safety and efficacy: actual functional recovery and retention (see fBNCI project, Grosse-Wentrup et al., 2011, Belda-Lois et al., 2011); b) Compare BCI based technique with use of only conventional methods, and with e.g. FES only (Shih et al, 2012).
Competing new technologies	tDCS; (e.g. Dayan et al, 2013); Virtual reality; games; Robot-aided rehabilitation (eg. Tyromotion Amadeo).
Expected advantages/disadvantages of BCIs compared to competing new technologies	1) tDCs: quite some evidence for effectiveness available (Sandrini and Cohen, 2013). Some evidence of added value in controlled trials (Kim et al., 2013). Low cost. 2) Games are engaging, motivating. Sparse data available, which suggests that it actually adds to result of therapy. Games are cost-efficient and a number of them already available. Developing therapy-specific games is quite expensive, however (Lohse et al., 2014). 3) Some robots already clinically available. Robots are quite large, not easy to setup at bedside and therefore not available quickly after stroke (Belda-Lois et al., 2011). EEG-BCI-FES will be smaller and applicable at bedside. Robots are very expensive. Moderate evidence for effectiveness already present (Belda-Lois et al., 2011). [From Focus Group:Robots can ensure repeatability without monitor what happens in the brain. Provide high customization of the devices according to primary user characteristic]
Fields with shared benefits (synergies)	Medicine: neuromodulation; diagnostics based on EEG may benefit from accurate detection of brain states (according to functional recovery) as well as adequate dry-electrode systems. Robotics: cognitive robotics benefit from accurate detection of motor intentions and brain states.

What is required to make this BCI solution commercially viable?	Cost reduction, usability, robustness, reliability, getting towards a functional device, clinical trials (to prove benefits in general, usability, …), adoption by users, healthcare system. Rehab centers must be convinced of its clinical efficacy vs. standardised therapy. Possible use in acute and subacute post-stroke rehab in hospitals.
Incentive for industry, why would industry be interested?	Large Market Size
Time to market	Mid-term (approx. 10 years)
Major milestones for product success	Research and technology development (RTD) needed to improve technical specifications (e.g. sensitivity, power consumption, ...), usability, robustness, reliability, getting towards a functional device, clinical trials (to prove benefits in general, usability, …), adoption by users, healthcare system
Recommendations	Feasibility/safety studies; Sponsored multi-centric RCT to prove BCI-driven FES system clinical efficacy for upper limb rehab after stroke; Improvements of Usability

D.1.3.2 Seizure detection and suppression in epilepsy

Susan is a 30-year-old woman with severe frontal cortical epilepsy. Her seizures come unexpectedly, and when she gets a seizure, she falls on the ground, often injuring her head, sometimes severely. She has tried multiple types of drugs, but none of them had the desired effect. Using non-invasive brain imaging methods, neurologists have found that the source of her epilepsy extends into eloquent cortex, which means that surgical resection will not be possible. Her neurologist explains a third option to her: a small, implantable device that detects when a seizure is coming, and which is then able to provide a warning signal and at the same time produces a specific electrical stimulation sequence in an attempt to stop the epileptic discharges before they are full-blown seizures.

Susan chooses to go for this option. During surgery, she receives two strips of four electrodes covering the relevant part of her brain surface. Small wires connect the electrodes to a miniature sensing/stimulation device that is firmly fixed to the skull. Each time a seizure onset is detected, the sensing/stimulation device generates a tiny a tickle on Susan's scalp, warning her to sit down quickly. At the same time, the device also produces electrical pulses at the site of the electrodes to stop the seizure from developing further.

A year after the implantation, Susan considers her quality of life greatly improved. Although she sometimes still has a seizure without a warning sign and without the neurostimulator stopping it, the number of seizures has decreased dramatically, and most of the time, she is able to sit down in time and thereby prevent injury.

Primary users	Epilepsy patients
Secondary users	Families, caregivers
Tertiary users	Neurologists, surgeons, health care system, society, insurance companies
Target group size	Large ~65 million people worldwide have epilepsy, 2/3 of them are helped with drugs, another 8% with surgery, the rest (~16.5 million people) may be considered for stimulation treatment (i.e. vagal nerve stimulation, non-invasive stimulation, invasive stimulation)
Market size	Large
Current treatment/options	1) Anticonvulsant medications (effective in about 2/3 of patients); 2) Surgery (effective in about 8% of patients) 3) Vagal nerve stimulation
Cost of current treatment/options	Costs of epilepsy comprise: - Direct healthcare costs (e.g. diagnosis, treatment); - Direct non medical (e.g. accomodations, informal care); - Indirect costs (e.g. the costs of loss of productivity due to seizures, unemployement, adverse effects of drugs andthe visits to a physician) - Intangible (e.g. pain, lost of quality of life) In USA the seizures result in direct economic costs of about one billion dollars in Europe of around 15.5 billion Euros in 2004.In 2001 India epilepsy was estimated to result in costs of 1.7 billion USD. Vagal nerve stimulation is about 40000 USD per person.
Advantages/disadvantages of current treatment/options	When patients are admitted for surgery, the average time from the onset of the seizure to the surgery is 20 years. Disadvantages of surgery: - May cause complications such as infection, hemorrhage, 0.1% is the mortality rate of patients who underwent the surgery; - May cause function loss, such as hemiparesis, visual field defects etc. Advantages of surgery: - if successful, can be a complete cure of the epilepsy Disadvantages of drug therapy: - 30% the patients continue to have seizures despite the drug treatment; - many AEDs have side effects Advantages of drug therapy: - No surgery with associated risks Disadvantages of vagal nerve stimulation: - Doesn't work in a substantial proportion of patients - Surgery required to implant neurostimulator - Stimulation of vagal nerve is perceived to some extent
Who pays?	- Patient; - Private health insurance companies (eg. Switzerland, US); - Public health care system (eg. Italy, Spain, UK, Germany);
Expected advantages/disadvantages of BCIs compared to current treatment/options	BCI for seizure interruption and warning (i.e. responsive neurostimulation) can be the only option for refractory epilepsy that have a focus in the eloquent cortex
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Proof of long term efficacy and safety (risk-benefit ratio)

Ethical issues	- Careful management of patients' expectations, especially since neurostimulation generally is applied as a last resort, when medication and surgery are not effective or possible. - Issues of justice, invasive stimulation systems are very expensive - Issues related to the 'burden of normality', i.e. the fact that successfully treated patients are suddenly disease-free and normal, which could have psychological consequences
BCI technologies needed	- Studies to determine which trigger (seizure onset or predictor of seizure) should be used to switch on the stimulator, and to determine if this needs to be a subject specific feature or not - Similar to open-loop stimulation solutions: more knowledge about stimulation paradigms and their effects on networks - Similar to open-loop stimulation solutions: more knowledge about which brain area to stimulate for which kind of epilepsy - Develop a manner to add the warning 'tickle'
Competing new technologies	- Open-loop (scheduled, continuous) neurostimulation devices - Non-invasive stimulation (transcranial electric stimulation, transcranial magnetic stimulation)
Expected advantages/disadvantages of BCIs compared to competing new technologies	Advantages: - Responsive stimulation (ie BCI) could be patient-tailored in terms of location and stimulation parameters, and therefore more effective than open-loop stimulation - Less power consumption than with continuous, scheduled stimulation - In 1 RCT that has been performed so far on responsive stimulation, it was well tolerated and quite effective Disadvantages: - Surgery can lead to complications, such as infection or haemorrhage
Fields with shared benefits (synergies)	DBS in general
What is required to make this BCI solution commercially viable?	Acceptance for medical treatment
Incentive for industry, why would industry be interested?	Number of users could be high enough for selling
Time to market	Short term (<5 years). Responsive neurostimulation for epilepsy has recently been approved by the FDA.
Major milestones for product success	Large and long term clinical trials that demonstrate effectiveness and safety in multiple types of epilepsy
Recommendations	Must be shown in a convincing big group of studies to be taken over by medicine

D.1.3.3 Cognitive stimulator

“Why can’t I remember in which hotel we are staying?” Lara’s colleague realised that her partner (59 years old) might need some help for attention and day-to-day memory, after she got lost in a business trip to Paris, a well-known city for both of them. After visiting her doctor and neurologist, Lara was diagnosed with mild cognitive impairment. She learnt that for some people

with this diagnosis, memory loss will be the first sign of Alzheimer's disease. “Is there any chance to prevent that?”, she wondered. Her doctor stated that intellectually stimulating leisure activities such as card games or crossword puzzles, as well as keeping a socially active life might help her to reduce the risk of Alzheimer's or at least to delay the associated symptoms.
To keep her motivation alive, Lara borrowed a novel product based on BCIs and intended for cognitive stimulation with personalized neurofeedback methods. She just needs to wear a thin headband and a fancy wearable bracelet. The first device monitors her brain activity to track Lara's attention and concentration to a specific task of her choice. The wireless bracelet intends to refocus her again on her task with vibrotactile feedback that she feels every time she is lost.
Lara has been using the BCI cognitive stimulator at home for some time now. She loves playing card games with friends or solving crosswords puzzles. The BCI headband wirelessly sends brain activity to her smartphone, which presents visual stimuli based on self-learning algorithms that often help her to remember things and tricks for her games. She knows when to look at her smartphone thanks to her new bracelet.

Primary users	Dement patients may use BCI cognitive stimulation as preventive/rehab tool, ie. to reduce/delay cognitive decline and improve QoL - Mild-cognitive impairment (MCI) - Frontotemporal lobar degeneration (FTLD) - Alzheimer's disease (AD) - Stage 3/Stage 4 - Vascular dementia - Lewy bodies (DLB) - Parkinson's disease Patients that may use BCI cognitive stimulation as rehab tool: - post-stroke (subacute phase, chronic) sp. to prevent vascular dementia - TBI Healthy users: - Age-related (>65 years) may use BCI cognitive stimulation devices to prevent cognitive deterioration
Secondary users	Family, caregivers, hospice-like homes
Tertiary users	Geriatrics, GPs, neurologists, health system
Target group size	Based on dementia: Prevalence dementia (WHO 2012 report): 35.6 million people living in dementia worldwide. Western Europe: approx 7.3% people aged > 60 years As the world population ages, the frequency is expected to double by 2030 and triple by 2050. Neither healthcare nor financial systems are prepared to face the magnitude of the situation (WHO 2012 report)
Market size	Large

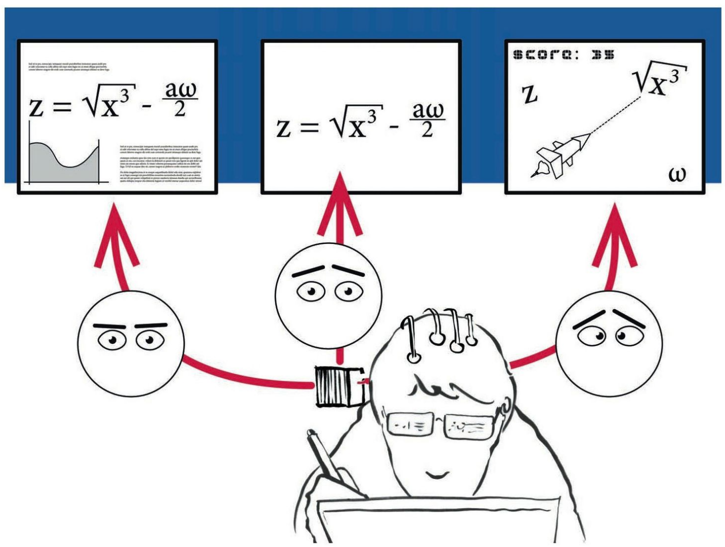
Current treatment/options	- Cognitive rehabilitation - FDA-approved drugs (Alzheimer’s disease): donepezil, galantamine, memantine, rivastigmine, tacrine
Cost of current treatment/options	probably high (this can only be answered by rehab centers)
Advantages/disadvantages of current treatment/options	Advantages: - expertise - effectiveness?? Disadvantages: - Current drugs help mask the symptoms of Alzheimer's, but do not treat the underlying disease.
Who pays?	Public healthcare system (eg. Spain, UK?, Germany?) Private health insurance companies (eg. US?) The patient (eg. US?)
Expected advantages/disadvantages of BCIs compared to current treatment/options	Aim: stop and delay cognitive deterioration by systematically compensating for functional losses BCI Benefits: - possible combination with traditional pharmacotherapy - possible combination with non-pharmacological treatment, ie. music therapy, art therapy, …. - efficiency in time (speedup) in combination with pharmacotherapy - BCI feedback in training - increase success rates - rehab at home possible BCI Disadvantages: - not that effective as an isolated tool.
From a user perspective, what needs to be resolved before the BCI solution can be applied?	- Easy and fast setup (hardware, software, features extraction and such) - complexity → high learning curve specially for elderly patients - Proof of safety; - Proof of efficacy.
Ethical issues	N/A
BCI technologies needed	- find specific cognitive stimulating tasks that allow EEG detection - EEG feedback - high motivating visual feedback translation in form of gaming to improve clinical efficacy in current/new cognitive rehabilitation methods Home rehab: Dry electrodes, easy wearable cap, light amplifier, wireless high-speed, real-time post-processing
Competing new technologies	Non-invasive brain stimulation (NIBS) (e.g. tDCS, rTMS) (eg. Flöel et al., 2014, Elsner et al., 2013)

Expected advantages/disadvantages of BCIs compared to competing new technologies	- still less invasive than NIBS
Fields with shared benefits (synergies)	- Neurorehabilitation - Logopedics - General learning - Gaming - Car-racing - highly competitive sports - Cognitively demanding tasks Combinations with competitors: - BCI feedback sys. in combination with NIBS (eg. Starstim “tDCS+EEG”, Neuroelectrics)
What is required to make this BCI solution commercially viable?	- Neurologists, opinion leaders, rehab centers must be convinced of its clinical efficacy - More chances of commercial viability if BCI is seen as in parallel to pharmacological therapy, and possibly other non-invasive brain stimulation methods.
Incentive for industry, why would industry be interested?	- Market size is large (eg. aging population, increased incidence of stroke events → vascular dementia) - Especially market value is high - Estimated market growth is high - Return of investment is high. - Competition is difficult (or market penetration by other industry stakeholders is difficult)
Time to market	*Mid-term (5-10 years). More chances of commercial viability if BCI (as form of feedback) is combined with NIBS (tDCS or rTMS, depending on FDA “clinical efficacy” approval), and other gaming techniques.
Major milestones for product success	Proof of concept studies. Research and technology development (RTD) needed to improve technical specifications (e.g. sensitivity, power consumption, ...), usability, robustness, reliability, getting towards a functional device, clinical trials (to prove benefits in general, usability, …), adoption by users, healthcare system
Recommendations	Multi-centric RCT to prove BCI clinical efficacy in cognitive rehab first: Patients: - post-stroke (subacute phase, chronic) - TBI - Alzheimer's disease - Mild cognitive impairment - Vascular dementia Cognitive tasks could range from selected attentional tasks to short-term memory tasks.

	Possibilities: - Pure BCI (feedback) + cognitive tasks vs. sham-BCI + cognitive (only cognitive tasks) - BCI+tDCS+cognitive tasks vs. sham-BCI-tDCS+cognitive tasks (only cognitive tasks)

D.1.4 Enhance

D.1.4.1 Neurotutor



Michael is in his last year of high school. His grades are good, but he is struggling with math. While researching efficient ways to study for his final exams, Michael finds several companies that offer adaptive learning environments. Adaptive learning environments provide optimal learning conditions for each individual student. Personal learning progress and skills are automatically tracked, and the information content is tailored towards the student.

One novel approach is called NeuroTutor, which measures brain activity of the student, which allows to accurately monitor the mental state of the student. Using information contained in the brain signals, the adaptive learning platform monitors the cognitive load, frustration level, and fatigue while using the education platform. This way, NeuroTutor adapts its content to the mental state of the student. When studying math, novel concepts are explained and introduced only if the student is susceptible for this content. Thus, NeuroTutor waits for a period when the student is highly concentrated and energized, yielding an individualized and improved learning progress for each student.

Michael and his parents decide to give NeuroTutor a try. Two days after this decision, they receive the headset in the mail, which allows to monitor brain activity. Michael is very happy with his decision when he realizes how comfortable and efficient it is to study with such an adaptive learning platform. Unlike before, he does not feel overwhelmed or frustrated by the complexity of the tasks and explanations while studying math.

Primary users	Students
Secondary users	Teachers, Professors
Tertiary users	Universities, Companies, Education centers
Target group size	Large (> 1 million students)
Market size	Very Large The number of potential users in Germany alone is between 0.95–1.2 million per year (users of auto-tutor, a competing product). The amount of students one can reach depends on the technology which is provided.
Current treatment/options	Static learning environments & adaptive learning platforms that function independent of brain activity
Cost of current treatment/options	There is no equivalent treatment. The only comparable treatment would be private lessons. The relevant literature estimates the expenses for private households at a minimum of 0.7 billion € per year for Germany alone.
Advantages/disadvantages of current treatment/options	Learning environment is not adjusted to the student
Who pays?	- The user (student) himself - Company (no knowledge in BCI) offering the teaching material - Companies (no knowledge in education & BCI) that educate their staff - Government, in order to improve public education
Expected advantages/disadvantages of BCIs compared to current treatment/options	Improved learning setup
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Easy to apply, affordable, comfortable
Ethical issues	Neural data is private data and therefore it needs to be protected.
BCI technologies needed	
Competing new technologies	real-time face analysis based on video
Expected advantages/disadvantages of BCIs compared to competing new technologies	The BCI has a unique selling point, as it is the only technology which can analyze brain activity in real-time and thereby reveal the raw and unfiltered mental state of a user/student.
Fields with shared benefits (synergies)	

What is required to make this BCI solution commercially viable?	(1) Develop user-friendly BCI hardware, which is robust and comfortable (2) Conduct usability studies that show that the tech works (effectiveness, efficiency, user satisfaction) and better than placebo or sham (3) Conduct acceptability studies
Incentive for industry, why would industry be interested?	BCI can improve the learning process and thus enable a better product.
Time to market	5-10 years
Major milestones for product success	(1) BCI device needs to be affordable, easy to apply and comfortable. (2) Reliability of Mental State Monitoring (i.e. measuring "Cognitive Load", "Attention Level" and "Level of Frustration") needs to be improved. (3) Data fusion of several streams of signals (EEG, Video, learning performance) (4) Adaptive Learning Platforms need to integrate the BCI into their framework.
Recommendations	(1) Conduct research studies to reach the above mentioned milestones. (2) BCI community should work with educational or learning experts

D.1.4.2 Enhanced user experience in computer games

Paul just bought the new X-Thought device for his video game console. This new input device is able to interpret his thoughts and feelings during his daily gaming session of Dark Souls III. Paul opens the box and a spider-like device unfolds. He puts the device on his head and wirelessly syncs it with his console.

He is thrilled by the enclosed demo game, which introduces him to the features and the functionality of the X-Thought device. Paul quickly plays through the demo game (as a gaming veteran, the tasks are no match for his experience). Finally, he starts playing his favorite game: Dark Souls III. As he slashes his way through hordes of evil monsters trying to block his way, he barely notices the subtle changes in volume of the effects and the changing gloom of the in-game graphics. At last, he comes under increasing pressure as some unexpected enemies try to get to him from the side. "This wasn't expected", he thought and tries to focus intensely on these opponents. Suddenly, his in-game avatar does a new unexpected move he has never seen before, and a fireball blasts his foes away. In the right corner off the screen, a small translucent X-Thought logo blinks and an in-game voice yells "X-Thought Fireball". "Wow! What a cool device!", says Paul to himself and continues his in-game tour.

Primary users	Video game players (gamers)
Secondary users	Video game manufacturers
Tertiary users	Publishers and manufacturers of gaming hardware
Target group size	187 million gamers in US alone
Market size	20.8 billion USD in US in 2012

Current treatment/options	Motion sensing devices (Kinect, Wii), virtual reality glasses (Oculus Rift), and smart game design in general.
Cost of current treatment/options	Kinect costs about € 150, Wii-mote $ 30,
Advantages/disadvantages of current treatment/options	Motion based controllers can often be triggered with small, simple artificial movements, reducing the players immersion in the game. Smart game design can anticipate the user's experience, but is one-size fits all.
Who pays?	End consumers (gamers)
Expected advantages/disadvantages of BCIs compared to current treatment/options	The game can be adapted to guide the player to a certain goal experience (e.g. relaxing, focused, challenged) of a part of the game. It could be more difficult to deceive than other inputs. Ultimately, it might provide a natural way to control super-natural powers in games (flying, magic spells).
From a user perspective, what needs to be resolved before the BCI solution can be applied?	The BCI needs to work robustly, every time, without calibration. Preparation time should be very close to zero, otherwise the cost of using a BCI will not outweigh its benefits. BCIs should offer an indication of mental states relevant to the experience of games, or provide fast actions to actively control aspects of the game.
Ethical issues	Biosignals are recorded, and used by commercial organizations. This might pose privacy issues.
BCI technologies needed	Cheap, robust and convenient EEG headsets, on-device EEG processing, robust output mental state classifiers, classifiers for fast user-initiated BCI tasks.
Competing new technologies	EMG wristbands that sense physical activity, casual gaming on tablets and phones, virtual reality glasses
Expected advantages/disadvantages of BCIs compared to competing new technologies	A clear disadvantage of BCIs is that one has to wear sensors on the head. As such they are intrusive. If they would work really well, the users intentions could be reflected in the game, thereby removing all barriers between player and game.
Fields with shared benefits (synergies)	Industrial design
What is required to make this BCI solution commercially viable?	Cheap EEG hardware, classification software that works out of the box.
Incentive for industry, why would industry be interested?	Unclear
Time to market	Some products are already on the market. For general use case 10 years.
Major milestones for product success	Milestones can be formed by progressively combining the following aspects. a) robust continuous classification b) zero calibration

	c) consumer grade EEG device d) fast user-initiated action selection e) robust mental state
Recommendations	- Focus on online BCI evaluated with games - Organize live competitions - Initiate contact with industry to forge common goals

D.1.4.3 Automatic emergency calls

Arina is an elderly woman, who has frequently tripped in the past. Nevertheless, she continues to live on her own. At the request of her grandchildren, she has accepted a novel medical alert system designed to call the ambulance in case she trips again. In addition to the standard emergency button, this system includes an acceleration sensor as well as a tiny electrode designed to monitor her brain activity.

One day, while hurrying to get dinner out of the oven, she tripped and knocked herself unconscious at the oven door. Recognizing the fall and analyzing the change in brain waves, her emergency system immediately called the ambulance qualifying the call with a tentative diagnosis of stroke. When the emergency doctor arrives, the system uploads the last 30 minutes of EEG data, allowing the doctor to quickly review Arina's brain states.

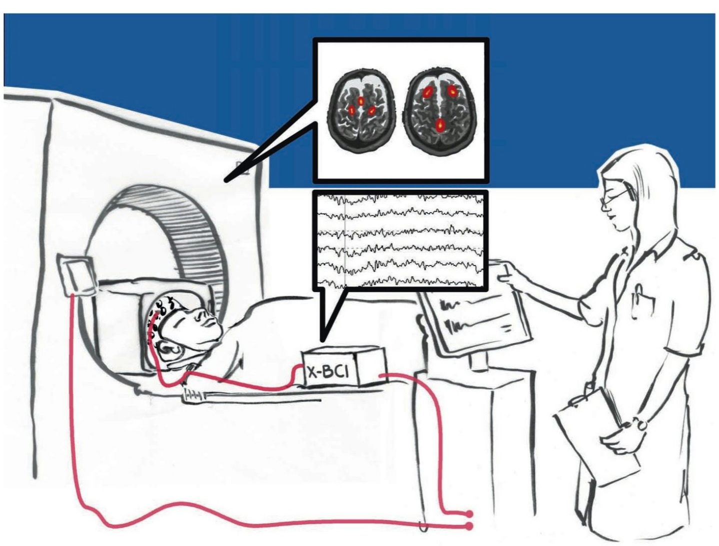
After waking up at the hospital, Arina is told that she had suffered a mild stroke which had caused her accident. However, due to the immediate alert and emergency measures, the doctors were able to prevent further brain damage. After Arina's discharge, her doctor wonders how many patients could have been saved had such an immediate alert system been available only ten years ago.

Primary users	Elderly
Secondary users	Family, relatives, caregivers
Tertiary users	Companies developing medical alert systems
Target group size	Large (elderly people)
Market size	2 Bn $ by 2020
Current treatment/options	Wearable medical alert system with fall detection (e.g. http://www.mobilehelpnow.com/products.php)
Cost of current treatment/options	~ 40 $ / month
Advantages/disadvantages of current treatment/options	Advantages: cheap, robust Disadvantages: provide limited information to doctors
Who pays?	private
Expected advantages/disadvantages of BCIs compared to current treatment/options	Advantages: potentially important information Disadvantages: false positives (however, FP not higher than with conventional system, as EEG is only evaluated when the standard system got activated)

From a user perspective, what needs to be resolved before the BCI solution can be applied?	Development of small, unobtrusive sensors very low power consumption
Ethical issues	Privacy of EEG data
BCI technologies needed	Wireless, dry sensors
Competing new technologies	none
Expected advantages/disadvantages of BCIs compared to competing new technologies	Advantages: provides otherwise unobtainable but important information
Fields with shared benefits (synergies)	Monitoring in the ICU, ubiquitous computing
What is required to make this BCI solution commercially viable?	User acceptance (depends on electrodes), demonstration that recognition of altered brain signals is reliable enough to reduce the time from onset of stroke to medical intervention
Incentive for industry, why would industry be interested?	Growing numbers of elderly patients, large market
Time to market	10 years
Major milestones for product success	Development of small, unobtrusive sensors with very low power consumption
Recommendations	Elicit information from hospitals and emergency doctors what kind of EEG-derived information would be most useful for their work.

D.1.5 Research tool

D.1.5.1 Research tool for cognitive neuroscience



Silvia works in the field of cognitive neuroscience. One of her research areas is decision making and free will, and more specifically the question "When is a decision made?". Silvia knows that brain-computer interface technology could offer unique possibilities to drive her work: BCIs can decode intentions and decision making in real-time, and the experiment could be adjusted on the fly to test hypotheses. However, none of her staff has experience with BCI technology.
Recently, she met the CEO of a company called X-BCI, which sells complete BCI systems. Their software platform is interfaced to the hardware of leading BCI hardware manufacturers. Based on the customer's demands, X-BCI will compile a complete BCI bundle, including all required software and hardware, and an instruction manual. The BCI toolkit is fully automated and easy to set up and use, but there is also an expert mode to change and add parameters and programs. Silvia's team only has to select one of the tasks in a graphical user interface and apply the neuronal signal sensor brace, which automatically makes multiple contacts with the scalp, on the subject's head. The BCI toolkit will automatically detect the type of hardware that is used for signal acquisition and stimulus presentation, perform signal acquisition and analysis, present stimuli and feedback to the subjects, track performance, and measure signal quality. Silvia's team does not need programming expertise and is able to collect good data from a large numbers of subjects in a short period of time. In her grant proposal, Silvia focuses on research without having to describe how the BCI system works. The reviewers of the proposal rated the proposal as innovative and, thanks to the use of the commercial BCI system, as feasible, and the application was approved.

Primary users	Researchers
Secondary users	Researchers
Tertiary users	Researchers (other stakeholders are funding agencies and publishers)
Target group size	Small
Market size	3000 (estimated number of research labs working in a related field)
Current treatment/options	Current technologies: EEG, fMRI, PET, NIR, MEG, ECoG etc
Cost of current treatment/options	Maybe not relevant, since BCI will not be a replacement, but more an addition to (i.e. implementation of feedback) to current research tools
Advantages/disadvantages of current treatment/options	Maybe not relevant, since those advantages and disadvantages will be exactly the same for BCI paradigms, since they make use of the same data acquisition technology
Who pays?	- Research grants - University - Maybe marketing companies
Medical certification?	No
Expected advantages/disadvantages of BCIs compared to current treatment/options	- If mobile brain recording systems become ubiquitous, an immense amount of data will become available that will be useful to study the relation between brain and behavior or cognition. - Possibility to provide stimuli only during specific brain states (brain-state dependent stimulation) or to online adapt parameters of an experiment (adaptive design optimization), which may be important to test specific hypotheses or to limit the duration of certain experiments. - BCIs form a

	novel type of circuits that are entirely determined by the experimenter, involve select components of the CNS, and therefore provide a unique research tool in neuroscience that may answer questions that cannot be answered otherwise. - BCIs can enable real-time interactive experimental designs
From a user perspective, what needs to be resolved before the BCI solution can be applied?	- Confidence in the functioning of the technology - Appropriate balance between standardization and individualization - Integration into the workflow of other technologies
Ethical issues	No specific issues. Ethical issues will be assessed for each research study separately. The BCI-related ethical issues (e.g. privacy issues, personhood, embodiment of technology, risks related to excessive use/maladaptive plasticity) will be covered by the studies.
BCI technologies needed	- Very high resolution recordings - Computational ability to stream and process large amounts of data in real time - For EEG: significant improvement of accuracy - Online noise reduction, artefact rejection and source reconstruction
Competing new technologies	None
Expected advantages/disadvantages of BCIs compared to competing new technologies	N/A (see Competing New Technologies)
Fields with shared benefits (synergies)	- New developments in sensor technology, e.g. high-field fMRI, optimized EEG sensors (dry, active, carbon-based, nanoscale biocompatible sensors), and multimodal sensors (e.g. EEG-NIR). - The (cognitive) neuroscience research field in general.
What is required to make this BCI solution commercially viable?	Sufficient demand by researchers of the field of Cognitive Neurosciences.
Incentive for industry, why would industry be interested?	Real-time validated experiments and paradigms are needed so that BCIs can be used as a cognitive or rehabilitation tool
Time to market	Short-term (1-3 years), however, “market” is the research field
Major milestones for product success	Customers (other researchers) need to be convinced of the usability of the BCI and its added value
Recommendations	Industry: Support for noninvasive and invasive technology

D.1.6.2 Medical examinations

Dr. Kimberly Bones is an ophthalmologist working part-time in her own office and providing expertise on occupational disability matters to a large insurance company. Introduction of automatized measuring equipment has greatly reduced her workload as compared to the times

when she still had to use eye charts for her work. However, she still feels that many of her methods are a burden, especially for her young and elderly patients.
One day she is contacted by her instruments' manufacturer who asks whether she was interested in trying a new add-on to their products. In essence, the add-on replaces the patient's button-click feedback, with feedback obtained from EEG recordings. For example, the add-on automatically knows whether a grating pattern was seen during acuity testing. While sceptical at first, she orders the easy-to-mount headset and the company's representative shows her the surprisingly fast setup. Wearing glasses herself, she is her first patient to take a complete EEG-guided optometric checkup. Standard procedures like visual acuity test, refractometry, and even high-density perimetry, which she always found especially tiresome, are performed fully automatized. Just near the end of perimetry testing, the system also indicates that she might be a bit tired and it might be best to pause a little for optimal results.
Summarizing her experiences, she estimates that the new system would make her work about 20% faster, but, more importantly, it allows her to perform highly reliable measurements even in children and her many elderly patients. In addition, being able to perform highly reliable measurements without having to rely on her clients' manual feedback might also increase the authority of her expert's reports.

Primary users	Patient
Secondary users	Medical Professionals
Tertiary users	Health insurance / Hospital
Target group size	150000 (Europe + US)
Market size	750,000,000 EUR
Current treatment/options	require active participation from patient.
Cost of current treatment/options	~13.000 EUR for a refraction unit
Advantages/disadvantages of current treatment/options	Results are susceptible to simulation/aggravation and tiredness.
Who pays?	Health Insurance, private
Expected advantages/disadvantages of BCIs compared to current treatment/options	pro: increased reliability and speed con: none with easy-to-use cap setup
From a user perspective, what needs to be resolved before the BCI solution can be applied?	Development of high-density user friendly (semi-) dry electrodes
Ethical issues	none
BCI technologies needed	current technology suffices
Competing new technologies	none

Expected advantages/disadvantages of BCIs compared to competing new technologies	Advantages: faster and more reliable than current standard technologies Disadvantages: higher costs for EEG
Fields with shared benefits (synergies)	image analysis
What is required to make this BCI solution commercially viable?	Proof increased reliability. proof that the examination is faster. Generate acceptance of the patients.
Incentive for industry, why would industry be interested?	unique selling point; If the examination time decreases, the insurance could save money in total
Time to market	3-5 years
Major milestones for product success	clinical tests to show reliability
Recommendations	Discuss with ophthalmologists and opticians their needs and views to such add-ons. Evaluate the possible acceptance of patients to use such devices.

D.1.6.3 Adaptive neurofeedback training app

Some years ago, Eva, a 32 year-old woman, had a bicycle accident. As a consequence, she sustained a severe traumatic brain injury, which caused serious impairments in both cognitive and motor functions. She was prescribed to use some conventional BCI-based assistive technology to perform basic activities of daily living. Unfortunately, common BCI paradigms for communication and control proved ineffective for Eva, as she is incapable of following the training instructions due to attentional and memory problems. To overcome these difficulties, Eva is offered to learn to use a BCI with a new method called Operant conditioning training, where she does not have to follow tedious and explicit instructions and all the learning is done intuitively and gradually. In the past, operant conditioning BCI training was associated with extremely long training periods. Luckily, such trainings have improved considerably in terms of time and Eva can learn using an adaptive BCI neurofeedback training. This has considerably reduced the required training time for Eva.

Adaptive neurofeedback training for BCI use has provided Eva with a general method to control several assistive technologies. She is now able to control a variety of system, such as brain-actuated speller, wheelchairs and her smart home. As a result of this, Eva's quality of life has considerably improved and she is now willing to actively participate to a number of social activities.

Primary users	All BCI users
Secondary users	Stakeholders (Prescribers, Traders, Payers,...)
Tertiary users	

Target group size	Very large (theoretically all BCI users)
Market size	It depends on the different applications of the BCI. In principle, an adaptive neurofeedback training app would have an enormous market size, very difficult to measure.
Current treatment/options	Normal BCI training without feedback
Cost of current treatment/options	N/A
Advantages/disadvantages of current treatment/options	Conventional BCI training paradigms are widely proven and more reliable
Who pays?	It depends on the specific application
Expected advantages/disadvantages of BCIs compared to current treatment/options	When compared different BCI training approaches, an adaptive BCI training excels because can deal with cognitive impairment which are necessary to comply with conventional BCI trainings
From a user perspective, what needs to be resolved before the BCI solution can be applied?	This super fast BCI trainings need to be widely proven and validated
Ethical issues	It does not apply. This will depend very much on the BCI application
BCI technologies needed	Better signal processing methods and algorithms
Competing new technologies	None at the moment
Expected advantages/disadvantages of BCIs compared to competing new technologies	N/A
Fields with shared benefits (synergies)	Better knowledge of cognitive functions and brain plasticity in both healthy and pathological brains
What is required to make this BCI solution commercially viable?	To investigate in new adaptive BCI training methods
Incentive for industry, why would industry be interested?	Market could be very large
Time to market	It depends on the accuracy and timings of such training method. It would take long time (>7-8 years) to have a training method able to provide high accuracies (>98%) in few seconds or minutes.
Major milestones for product success	This type of super fast training methods (e.g. neurofeedback) become widely used for several BCI applications
Recommendations	

D.2 Focus Groups

D.2.1 BCI-controlled neuroprosthesis (TUG)

Introduction

Three people filled out an online questionnaire: RR (neurorehabilitation specialist), IH (occupational therapist), and BK (occupational therapist).

Participants' background and previous experience with BCIs

RR has mainly worked with assistive devices for the upper extremities. IH and BK have used many different assistive devices, depending on the needs of their patients (e.g. Lokomat, treadmill with straps, crutches, wheelchairs, orthoses, …).
RR has intensively used BCIs in his own work. IH has never heard of BCIs before. BK was familiar with BCIs, but hasn't used them in his work.

Users' Opinion

RR thinks that the presented application was realistic, whereas IH didn't know if it was realistic, but it was certainly useful. BK was more critical, especially concerning the question who would pay for such a device. According to BK, people with SCIs lower than C5 would not need a BCI-controlled neuroprosthesis. People with lesions above C5 would probably benefit, but of course this depends on how many muscle groups the device can restore. Also, BK raised some concern about the target group of people who perform their work solely in front of a computer; BK thinks that only very few people can do all their work with a computer, so the target group could be rather small. RR agreed on the financial issues and on a potentially rather small target group (patients with denervated muscles cannot use the neuroprosthesis, but many SCI patients fall into this group). The potential benefit of the prosthesis could be low, especially when considering the high costs. Another issue could be the montage of the EEG cap, which could be rather complicated if it has to be exact.
According to RR, the main advantages could be (besides the restoration of function) therapeutic effects, such as reduced pain and/or spasticity. In addition, the prosthesis prevents muscle degradation and joint stiffness. Both IH and BK said that the neuroprosthesis would have many advantages over existing solutions (increased independence and social integration, more motivating, higher chances to get a job). IH even said that there are no competing solutions that would have the same results).

Ethical issues, Social aspects and long term risks

RR said that the number of involuntary actions must be well below the voluntary actions performed by the prosthesis. Ethical issues should be manageable as long as the prosthesis is used in patients who can really benefit, and as long as patients are informed in advance about the details of this device. IH also thinks that this is the most important aspect (to inform the patient in advance that functions will not be rehabilitated and that wearing an EEG cap and the prosthesis is required at all times). Long-term risks must be evaluated for invasive systems, this is not known currently.

Requirements

RR said that control must be robust with a very low number of errors. The patient should be able to autonomously use the device. Finally, it must be affordable (ideally covered by insurance). IH also said that straightforward operation is a requirement. BK said that the alleged benefits over existing solutions must be proven.

Conclusion

In conclusion, participants agreed that a BCI-controlled neuroprosthesis might be useful for a specific group of patients. However, it is not clear how large this target population is, because there might be severe exclusion criteria (such as SCI patients with denervated muscles, and people who mainly work with a computer).
A major factor besides technical feasibility will be cost. If such a device is very expensive and not covered by insurance, it will probably hamper widespread use.
Finally, all potential benefits must be proven – right now, the list of advantages sound a bit like a wish list, but especially the two therapists were skeptical or could not really assess how realistic a successful implementation is.

D.2.2 BCI-controlled neuroprosthesis (GUTT)

Introduction

In the context of the European project BNCI 2020, a focus group session (FG) with respect to the restore use case (UC) was organized. This FG aimed to collect experts' opinions regarding the pros and cons of the specific BCI application (UC) from different points of view.
Ten different people that included patients (individuals with spinal cord injuries, SCI), caregivers and different clinicians with expertise in people with SCI were invited to participate to the FG. An expert in focus group sessions was also invited to moderate the FG. None of the participants was involved in the project or in any other BCI project. One week prior to the FG, they were handed a document containing an explanation of the UC, together with some explanation pictures.
Of the ten people recruited for the session, seven finally attended to the FG. After a short presentation and introduction of the session contents, the moderator presented a short video of a BCI controlling a FES system and allowed the participants to ask any doubts with respect to the UC. When all doubts were resolved, the moderator started the session asking different questions both addressing several aspects of UC and actively encouraging discussion among the participants.

Participants

BP – END USER (C5 SCI) – male – 48 y/o

AN – END USER (C6 SCI) – male – 32 y/o
JM – CAREGIVER – female – 33 y/o
FD – TRAUMATOLOGIST – male – 55 y/o
JB – REHAB DOCTOR – male – 47 y/o
JP – OCCUPATIONAL THERAPIST – male – 34 y/o
MO – PHYSIOTHERAPIST – male – 37 y/o
MG – MODERATOR – female – 31 y/o

Participants' background and previous experience with BCIs

In general, they had heard about a BCI, some of them from news on TV, on the newspapers, and others because they had read scientific publications or on internet. However, none of them had previous experience with BCIs.

Users' Opinion

In general they had a positive opinion with respect to the instrument presented, although some of them (especially end-users and caregiver) expressed certain incredulity with respect to the viability of the proposed solution.

Doctors mentioned the tradeoff between what a system like this one would provide to the end-users and the nuisance of using it. They remarked the importance of changing the level of autonomy. They agreed that the instrument was difficult to imagine working perfectly smooth.

When compared to other existing therapeutic approaches such as tendon transfers or splints, they all agreed that the instrument would significantly increase patients' level of autonomy. Occupational therapist remarked that this could have impact not only in basic ADLs but also in both work and leisure spheres.

Clinicians in general opined that solutions need to be individualized since there are no general cases and thus an instrument like this might not be for everyone.
End users also raised the aesthetical aspect of this solution in particular, one of them explained that he would preferred to be fed by a friend (cause he cannot use his hands) before wearing a bulky cap with cables and different connectors. They all agreed that an implantable system would be the idea to pursue.

Ethical issues, Social aspects and long term risks

The users were concerned with the lack of control of the system when cognitive impairments or system malfunctioning.
In general, all felt that there no specific ethical aspects could be raised even with respect to the high price that a system like they expected it would have.
They also remarked some of the potential risks that the system would have. For instance, in an implantable system, they were concerned about the surgical risks. On the other hand, in an external device, they commented on problems with reproducibility and the difficulties in setting it up correctly every single time.
Other concerns mentioned were: spasticity that is present in several of the target users and malfunctioning of the system that may lead to skin and tissue damage.

Requirements

In general, clinicians claimed that the system would need to be extensively tested before prescribing it to patients. These tests would need to prove that the system provides a higher level of autonomy when compared to conventional assistive technologies (e.g. splints) or surgical approaches (e.g. tendon transfers).
In addition, electrodes for electrical stimulation warrant further investigation, it is not clear how they would perform to acquire certain levels of accuracy and in the long term.
Both end-users mentioned that it would be important to have both hands operating individually, although they found it hard to imagine.
Clinicians commented that an instrument like this one would not change the way rehabilitation is performed in daily clinical practice.
Caregiver mentioned that would be necessary to have the opportunity to test it in order to get a better idea of what the system is capable of.

Conclusion

The FG included a representative group of patients, caregivers and clinicians. All participants had the opportunity to share their opinions with respect to the UC; they also appreciated being involved in the early phases of development of a system like this one.
Clinicians were less skeptical with respect to the system and in general tried to imagine how it would work. Their main concerns were about the different individualization of the solution to be adapted to the different patients’ needs.

Caregiver was open to adopt a system like this, although she also found it difficult to imagine and stressed the importance of testing it to get to know the functioning of the system.
Patients were the most skeptical with respect to UC, and in general they would not use it unless it provided a huge leap in functionality and usability if compared to what they are currently using.
None of the participants found any ethical concern with respect to the instrument.

D.2.3 Research tool for cognitive neurosciences (UMCU)

Introduction

Considering the international character of the group of participants to this focus group (researchers from a variety of fields and countries), the focus group was held as a Skype Meeting, on December 1st, 2014. Participants were:

- JDH, Researcher in the field of Cognitive Neuroscience (Decision making)
- SL, Researcher in the field of Consciousness
- RR, Researcher in the field of Cognitive Neuroscience (among others Vulnerability for Depression)
- JC, Researcher in the field of Brain Development
- AS, CEO of a company providing EEG systems and BCI tools
- JH, BNCI Horizon 2020 consortium member, researcher
- GK, BNCI Horizon 2020 consortium member, researcher
- MS, BNCI Horizon 2020 consortium member, moderator

Participants' background and previous experience with BCIs

Most participants use EEG for their research (alone or in combination with other techniques). Also fMRI, fNIRS, EMG and physiological parameters such as pupil dilation, breath change and saliva changes were mentioned.
Most participants are familiar with the concept of BCIs and have heard of the tools before. Three of the five participants have previous experience with BCI systems, AS because his company is selling BCI solutions, and two researchers are currently involved in BCI-related projects and/or use BCI-related techniques (e.g. classification, real-time interactive experimental design) for their research. The two researchers that have no previous experience with BCIs were interested to see what it could add for their future research, e.g. the use of neurofeedback paradigms for cognitive training.

Users' Opinion

When asked about their opinion about BCI as a research tool, in which the BCI is described as a complete off-the-shelf kit, participants agreed that, despite the reduced complexity of such a system, too much standardization is undesirable. Currently, BCIs are not completely developed and there is not (yet) a lot of confidence in the tool (compared to e.g. EEG and fMRI). Therefore, when using BCIs for research, researchers need to be able to know about the specifics, and have the ability to adjust for certain details. Other reasons for the need to individualize BCI tools is that every experiment has its own requirements and that having in-depth knowledge about e.g. what a classifier output tells you about the brain may prevent incorrect use of the tool. An example was given about the analysis tools for functional imaging: a limited number of standardized packages have now become available. These are helpful, but also invite people with too little experience and knowledge to use it and draw potentially incorrect conclusions. Finally, one participant mentioned that for several research groups, monetary limitations might be more crucial than time. This participant would be more interested in buying a BCI system when it was cheaper and required more programming in the lab, than when everything was set into an expensive off-the-shelf system. A combination of some form of standardization with the ability to adjust details and program specifics seems an intermediate solution. AS mentions that such a system already exists (OpenViBE).

When asked if they can see BCI as an essential component of cognitive neuroscience, participants are moderately enthusiastic. It is considered a highly interesting option, and for certain research directions, motor-independent pathways may be(come) essential. For other applications, however, the added value is still unclear. Research itself may have to prove the value of BCI.

One participant states that the usability of BCI as a research tool is partly dependent on the underlying signal acquisition technique. Optimal use of BCI as a research tool may require a combination of high spatial resolution (comparable to fMRI) and high temporal resolution (comparable to EEG), in real time. Such a technique is not available yet. Invasive recordings (ECoG) were mentioned as a possible solution with high spatial and temporal resolution. However, the application of ECoG-based BCIs as a research tool is may be difficult considering the ethical issues and limited number of subjects available.

Ethical issues, Social aspects and long term risks

Participants do not see many ethical issues related to the use of BCI as a research tool. BCI itself does not pose an extra ethical issue that is not already covered by the general procedures of the studies themselves. They agree that ethical issues become more relevant when BCI is taking out of a research setting and becomes an actual application, for example responsibilities in cases of EEG-based control of a wheelchair or detecting decisions based on brain signals in military situations.

When primed with potential ethical issues such as maladaptive plasticity or other factors (within the research setting), participants agreed that this is not a problem (at least not more than with other neuroscientific research).

One issue that was mentioned is privacy and (related to that) public opinion when acquired data is going to be stored in the cloud and analyzed by dedicated companies. General public should be informed on what is possible and what is not possible and researchers should be pro-active in preventing negative public opinion.

Requirements

Features that should be guaranteed before people would consider BCI as a research tool to be a valuable solution are, according to the participants, more related to the signal acquisition techniques themselves (high spatial and temporal resolution). Also robustness, reliability and user friendliness are mentioned. Another issue that is discussed is online source localization. This is, according to the participants, currently a severe methodological issue that remains to be solved. It is, however, not related to BCI per se, but more to the acquisition technique in general.

Conclusion

When closing the discussion, it was asked for some final comments on the question if BCI as a research tool should be expedited. People agree that this is the case, it is interesting tool. Issues that are repeated by participants are the need for individualization of the tool (not a completely fixed off-the-shelf system), as well as user-friendliness, and the fact that the success of BCIs will depend on signal acquisition techniques such as fMRI and EEG, and that these techniques by themselves suffer from some problems (spatial, temporal resolution for example), the solution of which is considered a highly important step forward.

D.2.4 Neurotutor (TUB, UNIWUE)

Introduction

Online interviews have been carried out involving 6 experts (E1-E6) in the field of e-learning, applied Neuroscience/Neurotechnology and Education.

E1: Software engineer who has developed an adaptive e-learning environment

E2: Professor specialized in e-learning

E3: Scientist from London, with research interest in BCI-assisted learning

E4: High-School Teacher in Germany

E5: Neurotechnology Professor from Korea with expertise in BCI and Mental State Monitoring

E6: Engineering Professor who has developed an adaptive e-learning course for basic university entry-level mathematics

Participants' background and previous experience with BCIs

Two participants (E3 & E5) had an in-depth knowledge about BCI, the remaining four participants had not heard about the details of BCI technology prior to this interview. Every participant read the background material before the start of the interview.

E4 and E6 had previously applied novel teaching methods with (high-school / university) students. E1, E2 and E6 are experts with e-learning platforms that operate independently of physiological data.

Users' Opinion

Experts in the field of e-learning had a rather sceptical opinion about the Neurotutor use case. They had very practical concerns about content-integration (it is difficult to produce learning material which is adaptive to the user) and they reported the added value of a BCI to be questionable. They moreover claimed that state-of-the-art learning platforms are not yet exploiting the entire spectrum of the user data which is currently available (e.g. error rates).

The teacher [E4] as well as the experts in Neurotechnology expressed a positive attitude towards the Neurotutor use case on a long term and they highlighted the additional value of a BCI-assisted learning platform. The application of BCI in the adaptive learning framework is seen as a rather novel field which requires more basic research on both, the BCI and the adaptive learning framework. Moreover, the Neurotutor system is expected to be rather expensive and it remains questionable whether or not the added value is worth the extra money [E3 & E5].

Several experts [E3-5] underline that there is a significant market potential for the Neurotutor use case, which is also expected to grow in the next decades.

Ethical issues, Social aspects and long term risks

Data privacy is regarded to be critical for all other non-clinical application fields, as future developments might enable to extract further information from the data which is not known when recording the data. As a long-term social risk, the Neurotutor enforces the transition to an extremely achievement-oriented society. If BCI-assisted systems enabled a unique advantage, people who do not have access might be left behind [E1].

Requirements

Participants highlighted the importance of being able to extract reliable psychological parameters associated with increased learning success. Adaptive learning platforms rely on the ability to automatically change the course and presentation of learning material based on the interests and learning style of the user. This requires very dense annotation of the learning material, which not only poses substantial challenges to content-developers, but also requires further research into semantic-web technologies. From this perspective it is clear that building a BCI-augmented adaptive learning platform requires large investments. Thus, proof-of-concept and market studies are required to determine (I) whether BCI-augmentation can result in superior learning performance, and (II) whether such a product is financially viable.

Conclusion

All experts see long-term potential of BCIs in adaptive learning platforms. However, practical problems as well as methodological requirements were reported which indicate that a commercially viable and scientifically convincing product is not expected within the next years. While the market size is generally expected to be large, the unique added value of a BCI is still unclear. It remains an aspect of future research to investigate the effectiveness of mental state monitoring during learning.

D.2.5 BCI-controlled robot assistant (GTEC,EPFL)

Introduction

A focus group with 5 participants and two single skype interviews have been carried out. All discussions were recorded on audio tape and transcripts were created.
Focus group:

- BH: Expert in robotics and BCIs.
- MS: Expert in the field of VR and robotics.
- AP: Expert for telepresence and haptics.
- FT: Expert for immersive visualization.
- AK: Expert for telepresence and teleoperation.

Skype interview 1: GS: Expert for noninvasive and invasive BCIs.
Skype interview 2: LT: Expert for robotics, BCIs and telepresence.

Participants' background and previous experience with BCIs

The participants are experts in Virtual Reality, telepresence, haptics, robotics and BCIs. Some of them have experience with people with motor impairments through collaborations with clinical partners.

Users' Opinion

GS at first did not see any benefits that the BCI based telepresence solution would have, compared to current ones. But when thinking about possible future telepresence applications with a BCI, that has solved current limitations, then he would consider it very interesting. Other participants said, that this kind of solution is a topic of ongoing research. They considered the presented mockup to be feasible in future.
It was discussed, that the solution should be even more free. This means, that the interface must not be a humanoid robot. In some situations the user would maybe prefer to control a flying drone or only a small camera with a microphone. A meeting could be done also only virtually, via the internet.
A vision during discussion was, that in future, there could be avatars placed everywhere and a user can rent such an avatar.
The virtual representation of the user needs to be very good, in terms of facial expression and body language, otherwise it will be strange to communicate to a robot.
Limitations are seen in terms of the BCI with noninvasive EEG. LT had the idea of a hybrid solution that would merge signals from different BCI strategies but also residual motor functions of the user. The robot control needs to be done via some high level commands that could be contextualized by the system.

Ethical issues, Social aspects and long term risks

Several potential ethical risks were discussed. One is about information, for example the medical status of the user could be read by the system. Also, with some clever tricks one could read maybe other personal information of the user. For example when asking a question you could elicit evoked potentials or error potentials that the user cannot hide.
Another problem is the issue of access. If you had that device that would give certain people a lot of additional capabilities, maybe that device is expensive or it is available for some other reasons only to some people.
Problems of liability could also occur. If one assumes that this device produces an action that was not desired. Then the question arises: who is to blame? Is it the problem of the BCI manufacturer? Is it the problem of the algorithm designer? Is it the problem of the sensor company? Did the person really not intent to do the action?
A potential risk is also seen with the virtual embodiment itself: Ongoing research provides evidence that when you change the body, you change aspects of yourself. So if someone spends a huge proportion of his/her time in a body that is a robot, what effect that might have on aspect of their perception, their personality their attitudes, these things are very unknown. MS reported about a journalist called Nonny de la Peña, who spent many hours embodied in a robot. When she saw a video of the whole experience that she has just being through, she felt she was seeing it from the wrong place, because originally she has seen it from the position inside the robot and she found it very shocking to see it from a different viewpoint. And the other thing that happened was that when later she saw someone else embodied in the robot she felt very profound disgust as if someone has been taking her body and is using her body without her permission.

Requirements

Research and funding should concentrate on the BCI technology for new paradigms, more reliable BCI processing, classification and long term usability and stability of acquisition hardware.
GS said that he does not think that the use case will be ever possible with noninvasive EEG. He thinks that we would need a new imaging technique that could give us that reliability and detailed information about the brain with high spatial and temporal resolution. Others were more positive and definitely believed that it could be done with EEG.
The way a telepresence robot makes the user look is important, otherwise people will not use it if it does not make you look good or cool. The system should be cheap enough to be affordable for many people.

Conclusion

All participants liked the presented idea, though one was sceptical about the feasibility. It was agreed that the presented mockup would provide big benefits, compared to current solutions. The control needs to have context awareness so that high level commands can be used.

Research onto embodiment itself also needs to be done to investigate how this would influence the user's perception.

D.2.6 Hybrid BCI-driven FES for rehabilitation (FSL)

Introduction

The focus group on the Improve use case was held at the IRCCS Fondazione Santa Lucia premises. Eight participants were involved, including one chronic stroke patient, two medical doctors (a neurologist and a rehabilitation expert), two therapists with experience in stroke rehabilitation, one health care provider with a medical education, two engineers representative of two different companies (one new small medical robotics spin-off and an international biomedical company).

- MT: Stroke patient. Computer science engineer. Chronic left harm impairment.
- MTF: Biomedical Engineer, representative of a spin-off for medical robotics.
- RR: physiotherapist with experience on stroke rehabilitation, robot-based rehab.
- PG: Biomedical engineer working for a worldwide medical technology company, he has experience with deep brain stimulation and baclofen infusion pumps.
- GM: physiatrist with clinical experience, he works with robotic instruments and new technologies.
- PC: physiotherapist with extensive experience in rehabilitation after stroke
- AS: Health care provider
- AT: neurologist and policy maker
- Consortium: Francesca Schettini, Floriana Pichiorri

Participants' background and previous experience with BCIs

First, participants described their experience/skills with rehabilitation. The patient told his successful story about lower limb and walking rehabilitation. On the other hand, he showed disappointment and frustration about the poor recovery of his left upper limb; after a few bad experiences and with the passing of time, he lost enthusiasm and started learning compensatory strategies for the activities of daily living. The therapists stated that the approach presented in the Use-Case is actually very similar to what they actually do in the therapy,

guiding and correcting the movement attempt on-line and targeting correct planning of movement. However, the quality and methodologies of rehabilitation currently depend a lot on the provider (different in different rehabilitation clinics, and also between therapists working in the same place). The medical doctors confirmed that new technologies for rehabilitation at present are meant to support standard approaches as add-on. The health care provider stated that rehabilitation is quite poor as compared to other medical fields: poorly known and understood by the general public and also by healthcare providers.
With regard to previous experience with BCIs system, the patient participated to a motor imagery based BCI training for upper limb recovery while admitted, one of the medical doctors and one therapist had recruited patients for the same study. The others had no direct experience with BCI.

Users' Opinion

The patient on his side had a positive impression of the device described in the use case: "if it works, I would use it." Even just to train himself to something, to reinforce the enthusiasm that is often lost in the chronic phase. Therapists and doctors were also positive about the device mainly for the possibility to act directly on the brain (cortical areas relative to arm movement) with a top-down approach (this in contrast with robotic therapy which provides a mere repetition of the task with a bottom-up approach, which was considered less valuable). Altogether, they stated that the presented approach was based on solid rehabilitative principles (neuroplasticity). Nevertheless, rehab professionals consider this type of technology as a support to standard therapy (not a substitution for it) and they consider it especially valuable in the chronic phase (at home) to maintain the benefits achieved in the rehabilitation clinic in the subacute phase. The patient confirmed this impression stating that he would have never used such a device in the first months, when the physical contact and support of the therapist was very important to him, but he would use it now to keep himself active. All participants were skeptic about the possibility to use such a device at home alone without the therapist support, and in this context, the possibility of remote control emerged (telemedicine/telerehabilitation). This possibility seemed appealing to industry and policy makers given the increasing number of stroke survivors needing rehabilitation in the future (aging population) and the reduced resources available. Therapists and medical doctors believe that to be able to prescribe and use the device it is mandatory that they know it, in terms of functioning, indications for specific patients, duration and quantity of treatment for each situations. In this sense, while they foresee a possible future home use, they would want to see and use the device now with patients during standard therapy.

Ethical issues, Social aspects and long term risks

The ethical and social issues emerged were the importance of straightforward communication both to patients (false expectations) and to policy makers (if we say that this device can substitute for, eg. 10 therapist, then the politician in charge could decide to buy 100 of it, but it is not the right way to go). The health care provider stated: "This device is maybe the future but it cannot substitute for doctors and therapists". Therefore, first we must be sure that it works,

secondly, we must be sure that we can provide it to all patients (and guarantee a continuative support) otherwise social discrepancies might arise.
Other possible risks related to the use of the device were the possibility to cause harm (too much time spent using it, maladaptive plasticity). On his side, the patient stated that he would not care much about the effects on his brain now, if the device can help him to just regain the function of his affected arm, even for a limited time in the day, he would use it: “I don’t care if it makes me improve, it can help me to do things like holding a glass and such, in this chronic phase when I know that I cannot improve much, It is ok with me”.

Requirements

When participants were inquired by the moderator on the requirements of such a device, the following issues were listed by the health care provider: safety; low costs in production and management; user-friendly interface; adaptation to specific patients (not all patients can benefit from it). Industry representatives confirmed that usability and ease of use are very important and they added the following points: market size; efficacy; possible use of the device in other conditions (plurality).

Conclusion

All users classes opinions were positive about the proposed Use case. As the primary user stressed out, such device could reinforce the enthusiasm and could be very useful in the chronic phase (at home) to maintain the benefits achieved in the rehabilitation clinic in the subacute phase. The possibility to follow a rehabilitation program at home would allow to save economic resources, and this is very important considering the increasing number of stroke survivors needing rehabilitation in the future (aging population). However it should not be considered as a substitute of the rehabilitation therapist but as a support to standard therapy. More research and clinical trials are still needed in order to define therapy details (duration, quantity, indications,…) and it is necessary to avoid false expectations in patients and policy makers.

D.2.7 Unlocking the locked-in (EKUT, UNIWUE)

Introduction

The consultation of users was organized in different steps including one-to-one interviews, a group discussion and retrospective commenting of the transcripts. All interviews and discussions were recorded on audio or videotapes.
The one-to-one interviews included

- P1 – Caregiver and relative of an ALS patient

The group discussion included

- P2 – Clinician specialized on paralysis and neuromuscular diseases
- P3 – Professor and chief neurosurgeon specialized on stereotactic implantation
- P4 – Manager in a mid-size company specialized on brain implants

- P5 – Ethicist specialized on neuroscience and neurotechnology
- P6 – Research engineer developing assistive devices for paralyzed

Retrospective comments were performed by all participants and additionally by

- P7 – Clinician specialized on neuromuscular disorders and stroke

Participants' background and previous experience with BCIs

The focus group comprised a very heterogeneous group from academia, hospitals, industry and primary care. All participants have previously heard about BCI/BMI technology, but their theoretical and practical knowledge of this technology spanned over a wide range. While some of the participants have only heard about this technology through the media, others had deeper theoretical knowledge and only two participants were endued with practical experience in the application of brain-machine interfaces (BMIs).

Users' Opinion

All participants agreed that BMI technology holds great potentials and can drastically improve quality of life of individuals with lost capacities, e.g. to communicate or move.
The biggest concern of the whole focus group was that the BNCI in the described case was used to decode "inner" speech, a dimension some participants felt uncomfortable with, as it would eliminate the natural boundaries between the patient's "inner" and "outer" world having major ethical and social implications.
Also, it was the general opinion that implantation should be a very individual decision, as patients with progressive degenerative disorders or brain stem stroke are very heterogeneous across multiple dimensions. The participating primary caregiver/family member (P1) who has just recently lost her father suffering from fast progressing ALS emphasized e.g. that her father had great difficulties to adapt to his quickly deteriorating health. Faced with the reality of progressing paralysis, communication e.g. was not her father's biggest concern. The clinicians (P2, P3 and P7) emphasized that a main aspect in the decision to implant a device is the specific need of the patient and understanding of their situation and expectations. All participants agreed that creating unrealistic expectations on any end should be avoided. Although many participants of this focus group were familiar with the possibility to implant neurotechnology or even involved in actively applied or developing it in their daily life, it was the general opinion that the benefit of an implantation must always exceed the potential risks. The participants agreed that the use-case should rather extrapolate scientifically and technically feasible approaches (to avoid overstatements and unrealistic expectations) while not limiting the "replace" case to communication only.
In this context, a future vision for such devices was brought up in which a BNCI could e.g. replace deficient sensory capacities, e.g. blindness in late stages of ALS, using a closed-loop retina-implant or direct brain stimulation allowing perception of touch or other sensory qualities impeded in the individual patients. Also restoration of movement could be a target. Also other ideas that were going even further have been discussed, e.g. the possibility of a

neuroprosthesis for all brain functions including emotions (e.g. in LIS after brain injury with depression).

Ethical issues, Social aspects and long term risks

Such neuroprosthesis that replaces and restores a wide range of brain function initiated a vivid debate about “how far should we go”. The participants agreed that application of this kind of technology must be individually tailored and accompanied by various ethical considerations. At the same moment it should be clear that very similar ethical considerations apply as to any other assistive device. Given that the general public and also many clinicians are not aware about the normal or above-average quality of life in locked-in patients, availability of new assistive tools that allow such individuals to communicate and participate in social interactions were regarded as extremely valuable and might change the way the public is thinking about severe paralysis. The long-term risks and challenges associated with implantation of BNCI technology were also extensively discussed. In this context it was raised that the filed will most likely see completely new technologies in the field of brain recordings or devices that interact with brain physiology. It was thus suggested not to stick to a specific technique, e.g. ECoG, keeping this part rather open.

Requirements

Use of BNCI technology for communication is already reality today (P3, P4, P6), but the degree to which this technology will comply with specific standards, e.g. degrees of freedom, invasiveness, long-term stability, cosmetic dimensions etc. depends on multiple factors (P3, P4). Clearly, fast and broad implementation of the available technologies into clinical environments and end-users daily life should be systematically facilitated (P2, P7). At the same time, the potential of BNCI technology to replace lost function should be further investigated using existing hardware solutions, including ECoG or intracortical devices. New and innovative approaches that reduce the long-term risks associated with BNCI implantation should be explored head-on as this greatly limits their applicability at the moment (P6).

Conclusion

The focus group concluded that BNCI technology would play a major role to replace lost functions in a variety of disorders. The use case should be revised in some points to avoid misunderstandings (e.g. decoding of “inner speech”) and opened to replacement of other functions, e.g. movement, vision or other sensory qualities. Also, the technique used for recording the required brain signals should not be specified too well in order to account for future advancements and technical innovations.

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