BNCI Horizon 2020

FP7-ICT-2013-10 609593
Nov 2013–Apr 2015

Deliverable:	**D4.2**
Title:	**Report on current BNCI application scenarios and user groups v2**
Work package:	WP4
Due:	M15
Type:	☑ PU[1] ☐ PP[2] ☐ RE[3] ☐ CO[4]
Main author:	Febo Cincotti (FSL), Donatella Mattia (FSL), Floriana Pichiorri (FSL), Francesca Schettini (FSL).
Other authors:	Clemens Brunner (TUG) , Johannes Höhne (TUB) , Eloy Opisso (FPING), Rupert Ortner (GTEC), Ruben Real (UNIWUE), Surjo Soekadar (EKUT), Mariska Van Steensel (UMCU).
Abstract:	This deliverable integrates the contents of D4.1 with recommendations from stakeholders to promote the synergies between different classes of users. It includes the methodology used for the consultation of users and the results of such consultation. Focus Groups and Interviews were identified as the most suitable instruments for the purposes of this project. Focus Groups and Interviews were conducted by six different partners in six different Institutions (each one on a different use case) and a common procedure to apply the instruments was adopted. The results presented in this deliverable will be part of the WP4 contribution to roadmap.
Keywords:	Brain Computer Interface (BCI), Users'needs, User Centered Design (UCD), End-users.

[1] Public
[2] Restricted to other program participants
[3] Restricted to a group specified by the consortium
[4] Confidential, only for members of the consortium

1 Introduction

This deliverable contains recommendations from stakeholders to promote the synergies between different classes of users as defined in D4.1, and integrates the content of D4.1 with the results of a direct consultation of users.

We performed a research on the SOA of methods applied for the elicitation of users' needs and opinions in different contexts. Indeed according to the User-Centered Design approach, users should be continuously involved in the different steps needed for the development of a new technology. Before starting to design a new product, users should be interviewed about their need and expectations, and in this regard different situations can be identified (Kübler et al., 2014).

Hale (1986) described three situations in which elicitation of users' needs and opinion is necessary:

- **Designing a new system** - Here, the focus is on the purpose of the new system, the target end-user and relative needs and the context in which it will be used.
- **Customizing an existing system for different groups** - Here, the focus is on users' roles to see which aspects of the system they could best make use of.
- **Fine-tuning of an existing system** - Here the focus is on differences between individuals. Information systems almost always need continuous fine tuning because, even if clients' needs do not change, there is almost always room for improving the way information is delivered (optimization).

Analysis of user needs can be carried out with a top-down or bottom-up approach.

In the **top-down approach**, the researcher starts with the users' decision-making and works down to information required for problem-solving. For example, to determine the needs of potential BCI users, first the researcher should identify their goals (e.g., communication in daily life), and then identify the specific tasks, settings, and tools needed to reach these goals. The top-down approach is particularly useful to design a new system or to customize an existing system.

In the **bottom-up approach**, the researcher starts with the information used, asking users how useful it is for the decisions they have to make. For example, to study how potential BCI users interact with different kinds of AT system (e.g. eye trackers systems) and to build up a picture or model of the goals users are pursuing with these system. The bottom-up approach is particularly useful in those situations where the researcher is fine-tuning a new system, but can also be used when customizing or fine-tuning an existing system (e.g. add a BCI channel to an existing assistive technology software - Lindgaard et al., 2006).

2 Review of the existing methods to elicit Users Needs

User needs analysis must be done with all system stakeholders. Stakeholders are those people who, for one reason or another, can affect or be affected by a product (or the outcome of a product). Stakeholders may include different user classes (primary users, professional users, companies, policy makers, etc.).

Needs analysis should involve real users. Only real users can provide the understanding of real needs that is necessary for system development. It is important to address those people who will provide results that can be generalized to the whole group, since the researcher will be able to talk with a relatively small number of people (Adams and Cox, 2008).

2.1 Surveys and questionnaires

Survey and questionnaires belong to the scientific methods category; they produce results, which are replicable and generalizable to a broader population. These results can be used to predict future actions and can be transferred to other researchers so they can reproduce the process. It is important to consider that people may lie or misunderstand the question or even

give incorrect information to please the interviewer. Surveys should be used to understand what, how often and to what extent a person could be interested in using a new product, to get information from many people and to test a new idea. Indeed surveys allow the involvement of large numbers with low effort, and they can cover many topics, also ensuring anonymity and confidentiality. However the survey construction is a tricky process that the researcher should carry out with great attention, and he has to consider that the opportunity to provide further explanation of each question is limited; the possibility of a low response rate should also be considered.

2.2 Structured interviews

Structured interviews are systematic methods; their results are less replicable and generalizable than that of scientific methods. The interview must be planned before data collection and it must be focused on the purpose of the study. The collected results must be interpreted and summarized. The structured interviews allow researchers to go deep into a particular subject, give the chance to hear the stories and metaphors that the subjects use as they describe their tasks and environment and avoid the problem of having people intimidated by the presence of other users. Structured interviews can be used to get feedback on a new idea and to contextualize survey findings, however they require a skilled interviewer; the interview should be recorded and transcribed and sometimes recruitment of participants could be difficult.

2.3 Focus Groups

Focus Groups belong to impressionistic methods and range from simple brainstorming to group discussions combined with sorting, surveying and other tasks to elicit individual opinions in a more controlled manner. During a Focus Group, a group of people is asked about their perceptions, opinions, beliefs, and attitudes towards a product, service, concept, advertisement, idea, or packaging. Questions are asked in an interactive group setting where participants are free to talk with other group members. Results are not generalizable or replicable but they give researcher the chance to hear the words and phrases used by members of the user group of interest. Researchers can improve system usability by using this language when designing the system and when introducing it to users. An additional advantage is that more diverse groups may produce more and better ideas, heterogeneous groups can arise new and unexpected topics and information due to the synergies between different users classes.
Focus Groups should be used to get feedback on a new idea, to contextualize survey findings and to gather a wide range of responses and diverse views on a topic.

Table I: Summary of the characteristic of the main research tools used to elicit users' needs and collect feedback about a new idea/product

Method	Why	When
Survey	**•Large groups for low cost** **•Cover many topics** •Anonymity and confidentiality	•To understand **what, how often, to what extent** •To get information from many people **•To test a new idea**
Interview	**•Provides rich, in-depth info** **•Allows for follow-up questions** •Stories & quotes	•To understand **how and why** **•To get feedback on a new idea** **•To get in-depth information** **•To contextualize survey findings**
Focus Group	**•Ideas build** **•Diverse views on a topic** **•Collect info in a short time**	•To understand **how and why** **•To get feedback on a new idea** **•To contextualize survey findings** **•To gather a wide range of responses**

3 Focus Groups and Interviews to elicit users' needs

Within previous research projects, users have been interviewed about their needs and expectations about BCIs by adopting different methods (questionnaires, well-validated scales, interviews). Here we preferred the Focus Group instrument because, with respect to other methods, it allows to obtain a larger amount of data of excellent quality. Further, though it is usually planned and structured in advance, it is still flexible and allows deepening the topics discussed. One of the aims of the BNCI Horizon 2020 project is to foster synergies between different fields (HCI, Industries, Researchers, professional users), in this regard the group discussion, involving different classes of users, facilitates the expression of new views and information. Moreover, the heterogeneity of the group would allow to collect new information with respect to previous users surveys (Kitzinger, 1995).

We planned to carry out Focus Groups for each one of the five application scenarios identified by the consortium (replace, restore, improve, enhance, & research) and for each focus group we identified an institution leader according to its background and skills. Since Replace is the most extensive application scenario of BCI, we report two focus groups about it, considering both an invasive and a non-invasive use case. In a few cases where the Focus Group resulted to be not feasible, structured interviews were held addressing the same topics of the Focus Groups. Structure and main topics were thus aligned among partners (see Section 3.1) to obtain comparable results.

3.1 Focus Group Guidelines

General guidelines on how to prepare and carry out Focus Groups were delivered.

With respect to participants recruitment we decided to involve people outside the BCI field, in order to obtain new and unbiased opinions. Each focus group involved 6-10 participants with different skills. One week before the scheduled session each focus group leader sent the information material (see section 3.2) to participants.

For each Focus Group we defined a set of questions according to the questioning route method. The latter consists of a structured program of articulated and detailed questions, formulated according to the purpose of the research and organized as follows:

- Opening question: it requires a quick response and is intended to create a comfortable environment;
- Introductory question: introduces the topic of research and allows participants to start thinking about it. Generally, participants are asked to give a definition or an example;
- Question of transition: it anticipates the main questions and connects the topic with the purpose of the research. Inquires about the experience of the participant with the topic.

- Main Question(s): it allows collecting the information needed. Usually there are 2-5 main questions.
- Closing question: closes the session and allows participants to reflect on what was said during the discussion and to identify the most important point of the discussion.

To conclude the focus group the moderator summarized the issues raised, and asked participants to confirm the appropriateness of the synthesis of their views, and he asked if they had something else to mention (Zammuner, 2003; Stewart et al., 2006; Liamputtong, 2011).

Focus group discussions were video/audio recorded. The main identified conceptual categories were summarized according to the topics of the focus group and organized as follows:

- Participants' background and previous experience with BCIs;
- Users' Opinion;
- Ethical issues, Social aspects and long-term risks;
- Requirements;
- Conclusion and main results.

3.2 Information material

Focus group leaders recruited participants who were not experienced with BCIs. For this reason one week before the scheduled focus group participants received a document including:

- An introduction about the BNCI Horizon 2020 project and the general objectives of the focus group (i.e. collect feedback from users, no details about the questions to be discussed);
- An introduction to BCI technology focusing on the specific use case/application scenario to be discussed;
- Use case illustration (if available);
- Use case story;
- An additional paragraph focusing on some details of the device described in the UC (e.g. operating principle, hardware, etc).

The aim of the focus groups was to collect information about current solutions and technologies applying to the specific use case, opinions and suggestions about the proposed device, user's expectations and possible ethical and social issues.

4 Results

4.1 Replace: Unlocking the locked-in

Leader:	EKUT
Contributor:	UMCU
Participants	One-to-one interviews: • 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
Question 1	Introduce yourself and your relation with LIS patients
Question 2	Please describe the way you interact with LIS patients
Question 3	Have you ever heard about invasive BCI to restore communication in LIS patients?
Question 4	What is your opinion about the instrument that we presented in the mockup?
Question 5	What could be its main advantage with respect to current solutions?
Question 6	In your opinion, what are the limitations of this instrument?
Question 7	Do you see any ethical/social issue? *The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously): Informed Consent from CLIS patient and caregiver, Privacy issues, Risks related to implant,Frustration related to malfunctioning/reduced technical assistance at the end of the study, Equal opportunities across countries and social status*
Question 8	Which risks do you see related to the use of the proposed instrument?
Question 9	Which features must be guaranteed before you could suggest/consider it as a valuable solution?
Question 10	Is there something important that you want to add/emphasize?

4.1.1 Summary

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

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.

4.2 Replace (non-invasive): BCI Controlled robot assistant

Leader:	**GTEC**
Contributor:	**EPFL**
Participants	Group discussion 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.
Q1	Introduce yourself, your experience with telepresence, and your relation with people with temporary severe motor impairments
Q2	What kind of solutions did/do you adopt/suggest?
Q3	Have you ever heard about BCIs to manage telepresence applications
Q4	What is your opinion about the instrument that we presented in the mockup?
Q5	What could be its main advantage with respect to current solutions?
Q6	In your opinion, what are the limitations of this instrument?
Q7	Do you see any ethical/social issue? The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously): Privacy Issues, Personhood, Embodiment of Technology; Risks related to excessive use, maladaptive plasticity; Frustration related to malfunctioning; Safety and responsibility of unwanted/uncensored actions; Equal opportunities across countries and social status
Q8	Which risks do you see related to the use of the proposed instrument?
Q9	Which features must be guaranteed before you could suggest/consider it as a valuable solution?
Q10	Is there something important that you want to add/emphasize?

4.2.1 Summary

Here we summarize the results of a focus group with five participants and two single skype interviews. All discussions were recorded on audio tape and transcripts were created.

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, and 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 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 skeptical 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.

4.3 Restore: Spinal cord stimulation for reach and grasp

Leader	**TUG – GUTT**
Contributor	**EKUT**
Participants	Online Questionnaire 1. RR neurorehabilitation specialist; 2. IH occupational therapist; 3. BK occupational therapist. Focus Group 1. AN end user (C6 SCI) – male – 32 y/o 2. JM caregiver – female – 33 y/o 3. FD traumatologist – male – 55 y/o 4. JB rehab doctor – male – 47 y/o 5. JP occupational therapist – male – 34 y/o 6. MO physiotherapist – male – 37 y/o 7. MG moderator– female – 31 y/o
Q1	Introduce yourself and your experience with functional deficits.
Q2	What kind of aids do you currently use to compensate your deficit? (for end-users). What kind of aids do you suggest/apply? (for professional users)
Q3	Have you ever heard about BCIs to restore lost functions?
Q4	What is your opinion about the instrument that we presented in the mockup?
Q5	What could be its main advantage with respect to current treatments?
Q6	In your opinion, what are the limitations of this instrument?
Q7	Do you see any ethical/social issue? *The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously): Risks related to implant; Risk related to maladaptive plasticity; Frustration related to malfunctioning/reduced technical assistance at the end of the study; Agency, safety and responsibility of unwanted/uncensored actions; Equal opportunities across countries and social status*
Q8	Which risks do you see related to the long-term use of the proposed instrument?
Q9	Which features must be guaranteed before you could suggest/consider it as a valuable solution?
Q10	Is there something important that you want to add / emphasize?

4.3.1 Online questionnaire Summary

Here we first report the results of an online questionnaire. Three people filled out this 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 has not 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, FG 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.

4.3.2 Focus Group summary

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' 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.

Fig 1 Restore Focus Group participants

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 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.

4.4 Improve: Home independent rehab after stroke: an hybrid BCI driven FES system for upper limb

Leader	**FSL**
Contributor	GUTT
Participants	1. MT: Stroke patient. Computer science engineer. Chronic left harm impairment. 2. MTF: Biomedical Engineer, representative of a spin-off for medical robotics 3. RR: physiotherapist with experience on stroke rehabilitation, robot-based rehab 4. PG: Biomedical engineer working for a worldwide medical technology company, he has experience with deep brain stimulation and baclofen infusion pumps. 5. GM: physiatrist with clinical experience, he works with robotic instruments and new technologies 6. PC: physiotherapist with extensive experience in rehabilitation after stroke 7. Health care provider 8. AT: neurologist and policy maker 9. Consortium: Francesca Schettini, Floriana Pichiorri
Q1	Introduce yourself and your relation with stroke
Q2	Are/is you/your relatives doing rehabilitation? *(end-users)* What kind of rehabilitation approach are you suggesting/applying? *(professional users)*
Q3	Have you ever heard about BCI for stroke rehabilitation?
Q4	What is your opinion about the instrument that we presented in the mockup?
Q5	What could be its main advantage with respect to current treatments?
Q6	In your opinion, what are the limitations of this instrument?
Q7	Do you see any ethical/social issue? *The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously): Risk related to maladaptive plasticity, Frustration related to malfunctioning/reduced technical assistance at the end of the study, Equal opportunities across countries and social status, how to deal with different clinical outcomes or criteria after using the same system/device (would you use this in all stroke individuals?)*
Q8	Which risks do you see related to the long-term use of the proposed instrument? Do you think that the intensive/long-term use of the device could be harmful?
Q9	Which features must be guaranteed before you could suggest/consider it as a valuable solution?
Q10	Is there something important that you want to add/emphasize?

4.4.1 Summary

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 biomedical engineers representative of two different companies (one new small medical robotics spin-off and an international biomedical company).

Fig 1 Improve Focus Group participants

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 health care 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 type of users' 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 (in the subacute phase) but as a support to standard therapy or an instrument to maintain the benefits of early phase rehabilitation in chronic patients. 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.

4.5 Enhance: A hybrid BCI for use in an adaptive learning environment

Leader:	TUB
Contributor:	UNIWUE
Participants	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
Q1	Introduce yourself and your relation with learning/adaptive learning environment
Q2	Which teaching/learning techniques do you use and which drawbacks do you see in current methods?
Q3	Have you ever heard about passive BCI to monitor mental state during adaptive learning?
Q4	What is your opinion about the instrument that we presented in the mockup?
Q5	What could be its main advantage with respect to current solutions?
Q6	In your opinion, what are the limitations of this instrument?
Q7	Do you see any ethical/social issue? *The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously):Privacy Issues, Personhood, Embodiment of Technology; Risks related to excessive use; Equal opportunities across countries and social status (selective enhancement)*
Q8	Which risks do you see related to the use of the proposed instrument?
Q9	Which features must be guaranteed before you could suggest/consider it as a valuable solution?
Q10	Is there something important that you want to add/emphasize?

4.5.1 Summary

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

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 skeptical 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.

4.6 Research: Research tool for cognitive neuroscience

Leader:	**UMCU**
Contributor:	**TUB**
Participants	1. JDH, Researcher in the field of Cognitive Neuroscience (Decision making) 2. SL, Researcher in the field of Consciousness 3. RR, Researcher in the field of Cognitive Neuroscience (among others Vulnerability for Depression) 4. JC, Researcher in the field of Brain Development 5. AS, CEO of a company providing EEG systems and BCI tools 6. JH, BNCI Horizon2020 consortium member, researcher 7. GK, BNCI Horizon2020 consortium member, researcher 8. MS, BNCI Horizon2020 consortium member, moderator
Q1	Introduce yourself and your research field.
Q2	Which instruments do you currently adopt to carry out your studies?
Q3	Did you ever hear about BCI systems and their potential applications as a research tool?
Q4	What is your opinion about the instrument that we presented in the mockup?
Q5	What could be its main advantage with respect to current and foreseeable solutions in your research field?
Q6	What are the limitations of this instrument, and which features must be guaranteed before you could suggest/consider it as a valuable solution?
Q7	Which risks and ethical/societal issues do you see, related to the proposed instrument? *The moderator, after a preliminary free discussion, can suggest the following issues (if they do not emerge spontaneously):Privacy Issues, Personhood, Embodiment of Technology; Maladaptive plasticity*
Q8	Should the development of 'BCI as a research tool for cognitive science' be expedited?
Q9	Is there something important that you want to add/emphasize?

4.6.1 Summary

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' 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.

5 Conclusions

The results of Focus Groups and interviews provide an overview of the users' opinions on BCI technology and its potentials applications and will be integrated in the final version of the roadmap. Each use case gives a specific example of how BCIs can be applied in the future, and depending on the specific application scenario, different topics have been identified. Some topics and issues were transversal to more than one Focus Group:

- Demonstrate benefits with respect to current available solutions, and, especially for invasive systems, benefits need to exceed risks: new BCI-based technologies must be reliable, usable and stable. Signal acquisition and signal analysis should be improved.
- Avoid social stratification and selective enhancement: new technologies, for both medical and non-medical use, must be available to everyone. In this respect money is an issue, new technology should be not expensive to be accessible to everyone.
- User motivation and personhood: system performance must match user's expectation and the indications of BCIs should be clear. Communication with media and policy makers should not create false expectations in potential users and general public. Researchers should pay attention to how the concept of personhood could change if interaction with computers becomes more direct using a BCI and consider how embodiment of technology would influence the user's self-perception.
- Privacy and Data managing: it is important to protect users privacy and to declare who can access the data and how data could be used (Enhance: "as future developments might enable to extract further information from the data which is not known when recording the data."). The system should not reveal inner thoughts and should allow avoiding "uncensored actions".

6 References

Adams, A and Cox, A. L. 2008. Questionnaires, in-depth interviews and focus groups. In: Cairns, Paul and Cox, Anna L. eds. Research Methods for Human Computer Interaction. Cambridge, UK:Cambridge University Press, pp. 17–34

Hale, C., 1986. Measuring job satisfaction. Nurs. Times 82, 43–46.

Kitzinger, J., 1995. Qualitative research. Introducing focus groups. BMJ 311, 299–302.

Kübler, A., Holz, E.M., Riccio, A., Zickler, C., Kaufmann, T., Kleih, S.C., Staiger-Sälzer, P., Desideri, L., Hoogerwerf, E.-J., Mattia, D., 2014. The User-Centered Design as Novel Perspective for Evaluating the Usability of BCI-Controlled Applications. PloS One 9, e112392. doi:10.1371/journal.pone.0112392

Liamputtong, P., 2011. Focus Group Methodology: Principle and Practice. SAGE Publications Ltd, Los Angeles.

Lindgaard, G., Dillon, R., Trbovich, P., White, R., Fernandes, G., Lundahl, S., Pinnamaneni, A., 2006. User Needs Analysis and requirements engineering: Theory and practice. Interact. Comput., Special Theme Papers from Special Editorial Board Members (Contains Regular Papers) 18, 47–70. doi:10.1016/j.intcom.2005.06.003

Stewart, D.W., Shamdasani, P.N., Rook, D., 2006. Focus Groups: Theory and Practice, 2nd edition. ed. SAGE Publications, Inc, Thousand Oaks.

Zammuner, V.L., 2003. I focus group. Il Mulino.