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ORIGINAL ARTICLE

Toward Independent Home Use of Brain-Computer Interfaces: A Decision Algorithm for Selection of Potential End-Users

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Abstract

Noninvasive brain-computer interfaces (BCIs) use scalp-recorded electrical activity from the brain to control an application. Over the past 20 years, research demonstrating that BCIs can provide communication and control to individuals with severe motor impairment has increased almost exponentially. Although considerable effort has been dedicated to offline analysis for improving signal detection and translation, far less effort has been made to conduct online studies with target populations. Thus, there remains a great need for both long-term and translational BCI studies that include individuals with disabilities in their own homes. Completing these studies is the only sure means to answer questions about BCI utility and reliability. Here we suggest an algorithm for candidate selection for electroencephalographic (EEG)-based BCI home studies. This algorithm takes into account BCI end-users and their environment and should assist in study design and substantially improve subject retention rates, thereby improving the overall efficacy of BCI home studies. It is the result of a workshop at the Fifth International BCI Meeting that allowed us to leverage the expertise of multiple research laboratories and people from multiple backgrounds in BCI research.

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Recent studies[1-4] have demonstrated fast and reliable control of brain-computer interfaces (BCIs) by healthy subjects and individuals with neurodegenerative disease alike, but these demonstrations have taken place either in the laboratory or in limited sessions in a home-based setting.

Noninvasive BCI technology allows people to use scalp-recorded electroencephalographic (EEG) activity as a control signal to perform a variety of tasks (eg, cursor control, word processing, e-mail, environmental control). Because BCI communication does not depend on neuromuscular activity, it can be an effective means of communication for people with severe motor impairments.

Present-day EEG-based BCIs have functional limitations, including modest rates of accuracy and low speed, as compared with other augmentative and alternative communication solutions operated by people with severe motor impairment.[5,6] However, as recently reported, BCIs can be used after eye-tracking systems fail.[7] Moreover, 1 report[8] has shown that a BCI can be less effortful to control than an eye-tracking system. Findings such as these suggest that a BCI may be the only viable option of restoring independent communication and autonomy for some individuals who are severely disabled.

Most BCI studies are conducted exclusively in the laboratory with healthy subjects, and many studies do not report online results. Such studies can provide valuable information about signal extraction, conditioning, and classification. However, the development of BCIs for communication and control depends on the individual user in a closed-loop design. BCIs that work in the laboratory need to work in real time and in real-life settings in order to give people capabilities that improve their lives. The translational research that seeks to establish the clinical value of a

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BCI must answer 4 questions: (1) "Can the BCI be implemented in a form suitable for long-term home use?" (2) "Who are the individuals who need and can use the BCI." (3) Can the individual's home environment support the BCI usage, and does s/he actually use it?" and (4) Does the BCI improve the individual's life?"[9(p325)] To allow for long-term studies that are suitable to investigate reliability, BCIs must be simple to operate, need minimal expert oversight, be usable by people who are extremely disabled, and provide reliable, long-term performance in complex environments.[5,7,10,11]

Thus, the BCI community is facing translational and reliability gaps that must be bridged if BCIs are to fulfill their primary purpose and justify the generous public support their development receives. The capacity of BCI-controlled applications to satisfy these demanding criteria can be determined only through long-term studies of independent home use by their target user populations. To date, only a few studies[7,8,12,13] of independent home use exist.

Despite the fact that EEG-based systems are relatively inexpensive and offer minimal or nonsignificant risk,[9] studies that include end-users with severe disabilities in the field require substantial commitments of capital and manpower from researchers. BCI users and their caregivers also make a substantial time commitment when they agree to use the BCI over weeks and months. What is more, these early BCI home users need to accept—at least at the very beginning of a study—that researchers may need to "occupy" their home.

To promote BCI technology for independent home use, the requirements for translational and reliability studies with end-users in their home environment need to be clearly defined. Four exemplary real end-users from the authors' laboratories are presented, and their potential for being included in long-term BCI studies is assessed. We propose an algorithm for decision making about inclusion of BCI end-users in the field.

Methods

The authors conducted a workshop at the Fifth International Brain-Computer Interface Meeting entitled "Independent Home Use of BCI: Requirements for Translation and Evaluation." Workshop participants (N=22) were BCI experts from around the world including many who had experience working with individuals with severe disabilities. The participants were divided into 4 groups. Each group received the case history of a person who had either expressed an interest in using a BCI himself/herself, or had a significant other express an interest on his/her behalf. Each group was instructed to discuss whether their petitioner was a candidate for BCI home use. The questions listed in table 1 served as a guideline for the discussion. The questions were derived from the experience of the authors and on the issue raised in the article by Neumann and Kübler.[10]

Workshop structure

Duration of the workshop was 3.5 hours. One hour 15 minutes were dedicated to introductory talks by the authors as the basis for the group discussions, 1 hour was allocated for the group discussions, and 1 hour 15 minutes were allocated for discussion of the results and summary. The participants represented the multidisciplinary nature of the BCI field. They included experts from the faculties of medicine, psychology, computer science, and engineering, as well as therapists and others who provide assistive technology and outpatient and home care.

List of abbreviations:

BCI brain-computer interface
EEG electroencephalography, electroencephalogram electroencephalographic

Table 1 Workshop participants had to propose an approach of how to answer the question, "Do you consider this person a suitable candidate for BCI use?" along the following questions of detail.

No.	Question
1	Is the individual a candidate for BCI use?
2	How is the individual approached, and how is informed consent obtained?
3	How is the individual's functional and cognitive ability assessed?
4	How is the environmental suitability of BCI use assessed?
5	What type of BCI control would be chosen and why?
6	What is the realistic outcome of BCI performance?
7	What criteria would be used to determine success?

Description of end-users

The case studies were drawn from people who the authors encountered within the past years. They were chosen to represent the breadth of people in potential need of BCI.

Candidate 1

Immediately after a multifocal acute ischemic infarction predominantly within the right posterior cerebral artery, candidate 1 was described as being in a locked-in state. After 2 weeks of recovery, he could track a physician's finger, but only intermittently. Two months poststroke, he was provided with an eye tracker. However, the eye tracker does not allow him to produce meaningful messages. His current means of communication is through subtle movements of the head, eyelids, or pupils. These movements are difficult for his caregivers and family to interpret.

Candidate 2

After an accident 21 years ago, candidate 2 was left blind, severely motor-impaired, and unable to communicate verbally. For some years postinjury, he maintained the ability to control a computer. After the loss of this computer control, even though he retained the ability to control his eye muscles and remained alert and aware, candidate 2 remained functionally locked in. In large part, this was because of neglect by his doctors and mistreatment by his caregivers. After many years, one of his caregivers began to communicate with him using a binary code (ie, eyes lifted indicated "yes"; eyes down indicated "no"), using pairs of questions that verified his response (eg, question 1: "Are you hot?" question 2: "Are you cold?"). Over time, he regained some muscular control through physical rehabilitation. Today candidate 2 is able to generate a sound if he wants to communicate and to use his tongue and his right arm to communicate commands in a partner scanning approach.

Candidate 3

Candidate 3 is a 63-year-old man with diagnosed amyotrophic lateral sclerosis, symptomatic for 4 years. His current

Amyotrophic Lateral Sclerosis Functional Rating Scale score is 3, and he has been 100% artificially ventilated for 12 months. Candidate 3 has had several strokes that have left him blind in the right eye. He requires glasses to correct his vision but declined them when offered and does not use them regularly. He spends most of his time in bed and is moved to his personal computer several times per week. He lives in a small 1-bedroom apartment with his caregiver and has nursing care during the day. One sister lives close by, but his children live at a distance. He previously worked as a sales consultant and had a great deal of computer experience. Wireless Internet service is available and used with his current communication device. The current means of communication for candidate 3 is an Eye Response ERICA communication device. He is very proficient with the ERICA. His low-tech communication consists of 1 blink or jaw movement for "yes" and 2 for "no." As a distress signal he makes a face (knit eyebrows, mouth open). The amount of space in his bedroom, where he would use the BCI, is very limited. His caregiver was very cooperative and interested in the technology. Although the ERICA system works well if it is calibrated correctly, it must be calibrated multiple times during a single use.

Candidate 4

Candidate 4 is a 45-year-old man who experienced a heart attack 5 years ago and was resuscitated. He survived with a severe brain injury. Computed tomography revealed diffuse lesions in cortical areas and spared thalami. According to medical records, brainstem and auditory evoked potentials are normal, as are sensory evoked potentials. After 4 weeks of hospitalization and 2 months in rehabilitation, he was transferred to a nursing home. Despite his diagnosis, it is unclear whether he is in the locked-in or minimally conscious state. According to his wife, he communicates with eye blinks, and during a first visit he indeed showed some command following and seemed to understand the conversation. The patient presents with some uncontrollable tongue movement that seems to increase when he is excited. His wife is eager to participate in BCI sessions. She emphasizes that she would always be around when the researchers schedule training.

Results

Table 2 lists the categories provided by the organizers and used by the workshop attendees to evaluate the candidates for inclusion in an appropriate BCI study, and the results of this categorization.

The attendees of the workshop agreed that in addition to an acknowledged interest, a potential participant in a translational or long-term study of BCI use must be in need of assistive technology for communication and control. This excludes all healthy subjects and those with intact faculty of speech and sufficient limb movement to control reliably the variety of assistive devices (eg, wheelchair, software with multiple options) already available. Candidates or their legal representatives must be able and willing to provide informed consent. Candidates must be able to understand and follow instructions and to focus attention for the time required to produce the targeted brain signal. They must demonstrate sufficient control to complete the tasks described in the protocol—for example, communicate using words or phrases, produce device commands, or provide data to test for statistical significance. Further, significant others need to be in favor of the BCI home use and be willing to maintain contact with the BCI

Table 2 Guideline questions for determining candidacy for BCI home use*

Question	Case 1	Case 2	Case 3	Case 4
BCI candidate	Maybe not†	Yes, for rehabilitation‡	Yes, hybrid	Yes§
Consent	From patient with binary communication, video	Patient and caregiver	Easy, motor output available, also caregiver	Full AAC assessment
Cognition	Adapt items from standardized tests	Standardized tests adapted for yes/no answers	Interview + observation by caregiver	Medical records, able to say yes or no
Environment	Availability of caregivers, save environment, space	User wishes environmental control	Caregiver available, positive?	To be assessed next visit
BCI type	P300, RSVP, auditory; provide a switch	Staged intervention: MI, 20–30min, 2 channels— regaining motor skill	Visual, maybe auditory, hybrid?	MI training
Outcome	Reliable communication	Independent communication	Maintenance of function	Information about state of consciousness/ reliable communication
Success	User preference, ITR, independent use	ITR, independent use	QoL indicators	If he can say yes and no

Abbreviations: AAC, augmentative alternative communication; ITR, information transfer rate; MI, motor imagery; QoL, quality of life; RSVP, rapid serial visual presentation.

* Assessment of the 4 potential end-users of BCI technology along different categories.

† Maybe not, because candidate 1 may be in the minimally conscious state.

‡ Motor imagery training, because candidate 2 may improve in motor performance.

§ Motor imagery training, because candidate 4 has difficulties with fixation.

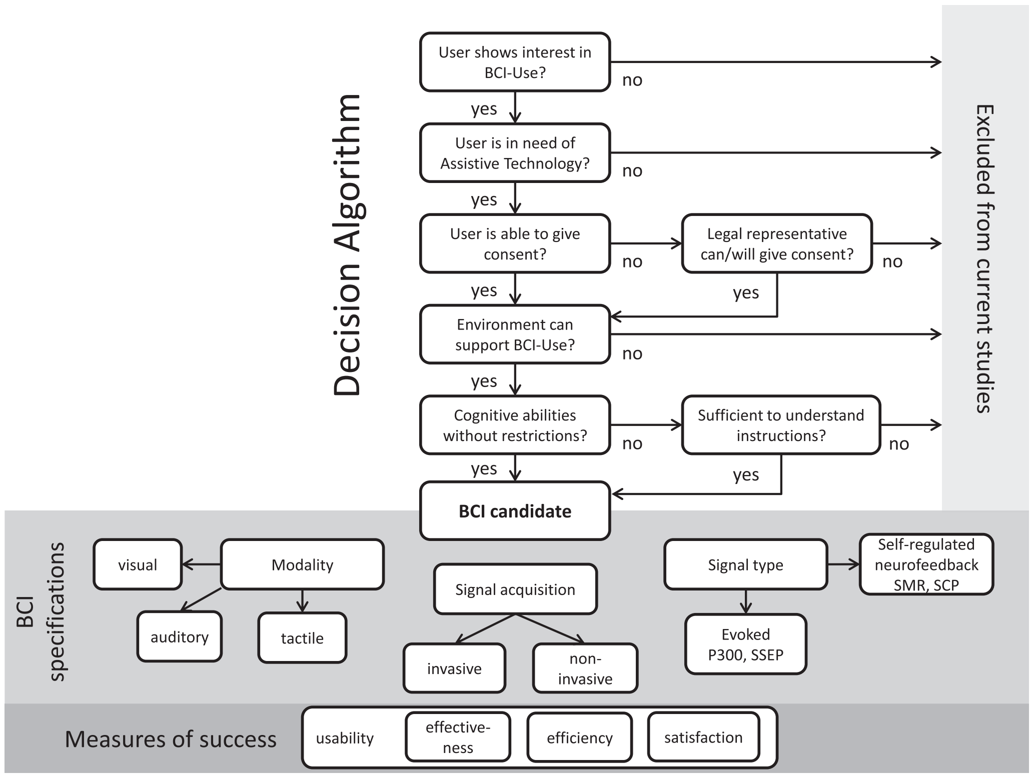

Fig 1 Decision algorithm for defining BCI candidates for translational and longitudinal studies. The algorithm ends with the decision "BCI candidate" yes or no. Then, it has to be decided which BCI would be the most suitable for the individual end-user and which measures of success are appropriate. Abbreviations: SCP, slow cortical potentials; SMR, sensorimotor rhythms; SSEP, steady state evoked potential.

group, to set up the end-user, and to answer questions for evaluation. If all those issues can be answered affirmatively, a person would be a suitable candidate for longitudinal externally valid BCI studies. Figure 1 depicts the proposed decision algorithm.

Discussion

We proposed a decision algorithm for identifying BCI candidates for translational and longitudinal studies. The cases introduced aim to demonstrate the wide range of potential end-users of BCI technology, including individuals who may require BCI as a tool for rehabilitation as well as those who require communication and control.[14-16]

Support and environment

We stated that the significant others who support BCI setup are the most important feature of the end-users' environment. Support is necessary because despite efforts to facilitate BCI setup[17] and calibration,[18] an end-user cannot yet use the BCI fully independently. Truly independent use will hardly be possible—or it can be argued, necessary—because the potential end-users will be severely ill and in most cases in need of 24-hour care. Although the prerequisites for the optimal physical environment for long-term BCI studies are not yet well defined, we argue that adequate space for the BCI device and EEG signal quality sufficient to operate the BCI are essential, and an environment that is minimally distracting to the end-user is preferred. Noise from electrical sources may impose severe obstacles to BCI operation, and interruptions or distraction may prevent the user from maintaining focused attention.

Cognition and understanding

Altered faculty of thought may also impede BCI training and independent use. Ideally, a full battery of cognitive tests would be applied to support the decision whether a person may be a BCI candidate. However, standardized cognitive tests are not adapted to locked-in end-users. Thus, no norms exist. However, several studies[19-21] have presented tests that can be completed with yes/no answers without requiring reaction time as an outcome measure. Further, in exemplary locked-in patients it was shown that BCIs can be used to apply cognitive tests[22,23] or even to detect conscious awareness if the patient is nonresponsive with regards to motor output, such as seen in the vegetative state after severe brain injury.[24-26] Thus, the assessment of the cognitive state of severely paralyzed end-users or even those in the locked-in state should be possible. A further issue to consider is the time needed for such an assessment. Several additional sessions with the patient will be necessary requiring additional time, person power, and financial resources. We argue that in many cases, an interview may suffice to assess whether the potential end-user will be able to follow instructions. When dealing with potential end-users in the complete locked-in state with no residual muscular movement, not even for a limited time, only the BCI itself can serve as a test for its potential usefulness for such a user. However, with respect to long-term studies to bridge the translational and reliability gaps, end-users with whom a reliable, albeit restricted interaction is possible may be preferred. For this reason, candidate 1 may be not a suitable BCI end-user to be included in a long-term study. Whether or not minor cognitive impairment prevents independent BCI use remains an empirical question, as neither event-related potentials nor the ability to learn from neurofeedback is prevented by restricted cognition.[27]

Provided an end-user achieves a positive outcome and is thus considered a BCI candidate, it has to be decided what kind of BCI to offer. Usually, it will be the BCI that is in the focus of research of the respective BCI laboratory. Ideally, however, one would be able to choose among the options depicted in figure 1 depending on the preference and brain activation patterns of the end-user. We intend this algorithm to be general purpose, suitable for *all* approaches to BCI; therefore, a complete treatment of all BCI options is not included.

Exclusion of candidates

As currently defined, the decision algorithm explicitly excludes candidates for technical issues—that is, if there are conditions in the home that preclude good signals or if there is no available caregiver. Considering the current and expanding research effort,[28,29] it may well be that the exclusion criteria will be modified in the future. For example, better EEG recording may become more tolerant toward electrical noise, and thus an electrically noisy environment would no longer constitute an exclusion criterion.

Outcome measures for evaluation of BCI-controlled applications

If a study is undertaken, measures of success need to be defined. Guidelines for user-centered design have already been proposed.[5] The user-centered approach provides a framework for study design using standardized outcome measures that allow us to compare different BCI-based applications for communication and control.[30] It includes an iterative process of development and feedback between researchers and end-users that leads to further refinement of the product. Within the user-centered design, usability is defined as effectiveness and efficiency of, and satisfaction with, the assistive technology device of interest. For BCI-controlled applications, effectiveness can be regarded equivalent to the accuracy of selections, and efficiency to the amount of information transferred per time unit and the effort invested (information transfer rate, workload). Satisfaction with a device can be assessed for general and BCI-specific aspects and includes the match between user and technology.[5,11,31] The results of this BCI-controlled application evaluation process may, in the future, contribute to refinement and elaboration of the currently proposed algorithm.

Validation of the algorithm

Translational BCI studies require considerable resources. They are conducted in the home, and their cohort includes individuals with orphan diseases. Data collection is time-consuming, takes place over weeks and months, and requires considerable investment on the part of the investigator. Many subjects have significant health issues that can suspend data collection for long periods and interfere with their ability to complete the study.

Study limitations

The algorithm presented here was informed by the experiences of the workshop organizers and attendees together with the limited number of published studies that describe BCI end-user selection and training in translational studies (eg, the study by Neumann and Kübler[10]). At present, the algorithm is theoretical and as such requires validation. We believe that using the algorithm will minimize the impact of the factors detailed above. In turn, minimizing these factors will contribute to successful data collection, make the results easier to interpret, and provide insight into logical next steps. Meta-analytic procedures (see http://handbook.cochrane.org/ for methods) may allow us in the future to validate the algorithm based on the reduction of these issues provided that at least some researchers use it as a basis for the inclusion/exclusion decision-making process. In this case, the value of standard study designs and cohort selection cannot be overstated, thus providing more information. We hope that adopting this algorithm will provide researchers with greater insight into BCI use and provide guideposts for the future.

Conclusions

The suggested algorithm may provide the basis to decide whether potential end-users of BCI-controlled assistive technology are suitable candidates for translational and long-term BCI studies. The different components of the decision algorithm have to be further refined. For example, in the future, more knowledge may be available about which environmental condition is decisive (eg, caregiver constantly present, no electrical noise, patient in a wheelchair). Also, it may be that cognitive abilities advantageous for BCI operation will be identified. With more knowledge about the biopsychosocial needs and requirements of end-users, the BCI community may finally be able to define indication criteria to select the most suitable BCI for the individual. The proposed decision algorithm to identify BCI candidates may constitute 1 pillar for bridging the translational and reliability gaps, and to facilitate independent home use of BCI-controlled applications.

Keywords

Feasibility study; Rehabilitation; Reproducibility of results; Translational medical research

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