

# NIH Public Access

Author Manuscript

Disabil Rehabil Assist Technol. Author manuscript; available in PMC 2015 January 01

## Published in final edited form as:

Disabil Rehabil Assist Technol. 2015 January ; 10(1): 11-18. doi:10.3109/17483107.2013.836684.

## A clinical screening protocol for the RSVP Keyboard<sup>™</sup> braincomputer interface

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## Abstract

**Purpose**—To propose a screening protocol that identifies requisite sensory, motor, cognitive, and communication skills for people with locked-in syndrome (PLIS) to use the RSVP Keyboard<sup>™</sup> brain-computer interface (BCI).

**Method**—A multidisciplinary clinical team of seven individuals representing five disciplines identified requisite skills for the BCI. They chose questions and subtests from existing standardized instruments for auditory comprehension, reading, and spelling;modified them to accommodate nonverbal response modalities; and developed novel tasks to screen visual perception, sustained visual attention, and working memory. Questions were included about sensory skills, positioning, pain interference, and medications. The result is a compilation of questions, adapted subtests and original tasks designed for this new BCI system. It was administered to 12 PLIS and six healthy controls.

**Results**—Administration required one hour or less. Yes/no choices and eye gaze were adequate response modes for PLIS. Healthy controls and 9 PLIS were 100% accurate on all tasks; three PLIS missed single items.

**Conclusions**—The RSVP BCI screening protocol is a brief, repeatable technique for patients with different levels of LIS to identify the presence/absence of skills for BCI use. Widespread adoption of screening methods should be a clinical goal and will help standardize BCI implementation for research and intervention.

## Keywords

locked-in syndrome; brain-computer interface; cognition; screening; augmentative and alternative communication

The authors report no conflicts of interest.

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**Declaration of Interest Statement** 

### Introduction

Locked-in syndrome (LIS) is a condition combining tetraplegia and anarthria with preserved consciousness. Classical LIS describes patients whose voluntary movement is limited to blinking and vertical eye movements. Individuals who demonstrate voluntary movement other than blinking or eye movement are said to have incomplete LIS, and those without any voluntary muscle function whatsoever are diagnosed with total LIS [1]. Possible causes of LIS include brainstem stroke or other vascular pathology, traumatic brain injury (TBI), and neurodegenerative conditions such as advanced amyotrophic lateral sclerosis (ALS) [2]. We extend the definition to include people with severe speech and physical impairments, that is, those who may have more motor function than is typically associated with incomplete LIS, but who cannot consistently rely on speech or writing to meet their communication needs. In addition to the aetiologies listed above, this larger population may include those with acquired neurological conditions or neurodevelopmental disorders such as cerebral palsy, muscular dystrophy, multiple sclerosis, Parkinson's disease and Parkinson's plus syndromes, and brain tumours. This significantly increases the number of individuals who fit within a definition of incomplete LIS, and offers a more inclusive perspective of their speech and motor function for communication and possible implementation of braincomputer interface (BCI), a technology that shows great promise for use by the LIS population.

BCI is a means of interacting with a computer that does not require volitional motor control; it relies only on brain activity. Among other things, BCI systems allows users to type messages for communication, use a computer for Internet access or environmental, or control a wheelchair or prosthetic limb, all without moving a muscle. The potential of BCI technology combined with other assistive technologies (AT) for functional use in the community is becoming a reality. Unfortunately, there is little agreement among BCI researchers and clinicians about how to identify and describe appropriate end users. At the 2013 International BCI Meeting, a number of BCI research groups presented posters on end user needs and BCI use in the home [3-7]. Each group described the end user in different terms. In fact, the BCI Meeting's published poster abstracts [8] include 11 types of end user descriptions in 41 abstracts. Most frequently, end users are described according to their diagnoses (e.g. ALS, epilepsy, stroke) or with regard to some loss of function (e.g. complete motor paralysis, patients with motor disabilities), or with a mix of both (e.g. severe motor disability due to brainstem ischemic stroke). Some abstracts mention LIS, with inconsistent reference to the level of severity or underlying diagnosis. Many descriptions are general and unclear. The time has come for accurate and precise descriptions of end users and their cognitive-communication skills for the implementation of clinically useful BCI technology. As with any new AT, the skills needed for operation and functional use must be determined, so that a comprehensive process can be implemented to match the best device to the user [9].

Cognition and communication are persistent challenges for people with LIS, and deficits in these areas may affect BCI use. Some individuals with advanced ALS have been found to have relatively high, even normal, information processing capacity and overall cognitive function [10], though deficits may be observed in executive function, learning, and memory [11]. Even so, ALS is frequently associated with cognitive impairment, specifically

frontotemporal dementia (FTD). In a study of 279 people with ALS, Ringholz et al. [12] found that approximately 19% demonstrated moderate or severe cognitive impairment consistent with FTD, 32% presented with mild cognitive impairment, and the remaining 49% were cognitively intact. LIS resulting from other diagnoses may create a very different cognitive profile. Schnakers et al. [13] conducted neuropsychological assessment with nine people with LIS resulting from ischemic brainstem lesions, and one from a traumatic brain injury. Only four of the 10 patients performed the tasks within normal limits. Rousseaux, Castelnot, Rigaux, Kozlowski & Danze [14] describe persistent moderate and selective cognitive impairment in 16 patients with LIS (nine patients with LIS resulting from brainstem stroke and seven patients with frontal or frontotemporal lesions). They noted impairments in auditory recognition (associative level), oral comprehension of complex sentences, delayed visuospatial memory, mental calculation and problem solving.

Communication skills are difficult to assess in the LIS population, particularly for those with total LIS. People with classical LIS can use blinking or eye movements for yes/no responses or partner-assisted communication methods, or to control a speech-generating device [2,15,16]. Those with incomplete LIS may have additional options for gestural communication or alternative access to a speech-generating device [17,18]. However, even these methods may not be reliable due to fatigue or variability in motor function [19], and those with degenerative conditions such as ALS may transition to total LIS and lose the ability to communicate even through blinking or eye movements [20]. A number of new access methods are being developed for people with severe neuromuscular impairments [21,22] so that they can use assistive technologies effectively for communication and computer control. BCI is one promising method.

Currently, there are no standardized screening instruments that have been validated for examining cognition and communication in the population of individuals with LIS, using minimal motor responses or simple yes/no responses. Adapted evaluations range from interviews to determine who is a good candidate for BCI [27], to hours of formal testing [28]. Many existing assessment tools designed for other populations require verbal and/or written responses, which people with LIS are, by definition, unable to provide. In addition, co-occurring deficits such as visual impairments [15,29] or central deafness [30] may prevent LIS patients from seeing, understanding or responding appropriately to stimuli.

There are no reports of screening protocols used to determine whether candidates for BCI have requisite cognitive-communication skills to even participate in formal evaluations. A screening technique is used to determine if a skill or deficit is present [31]. It does not require test validity or reliability since it is simply a means of observing, 'Is the skill present?' not 'How capable is the person with this skill?' A BCI screening protocol would probe whether a person with LIS has the requisite skills for BCI use, not what level of skill proficiency he displays. For screening purposes, Lezak, et al. [31] recommend using a combination of tests and subtests, including some that are sensitive to specific impairment, some to general impairment, and others that tend to draw out signs, to make initial determinations. The general benefit of a screening protocol is to provide the BCI community with a clinical framework that is brief and repeatable for initial identification of skills

needed for BCI use, and to reduce test administration time and fatigue in this very impaired population.

#### The RSVP™ Keyboard

The screening protocol described here was developed for use with the RSVP Keyboard<sup>TM</sup>, a new BCI that serves as a means of communication for the LIS population [32,33]. This noninvasive BCI is a spelling interface based on the P300 signal, and selects letters using joint evidence from an n-gram language model and electroencephalography (EEG) signals [34]. Other existing BCI systems, such as the BCI2000 with P300 speller [35,36], the Berlin BCI Hex-o-Spell [37], or the intendiX® SPELLER [38], allow people with LIS to access letters for communication and computer control, but they do not integrate a language model with signal detection for letter selection. Another unique feature of the RSVP Keyboard<sup>TM</sup> is the rapid serial visual presentation (RSVP) format of its user interface. The RSVP Keyboard<sup>TM</sup> quickly presents one large letter at a time on the screen (as shown in figure 1), thus reducing the visual-perceptual demands of a complicated display. Users are expected to visually attend to the computer monitor to spell a word or to copy words presented to them. Along with other BCI communication systems, the RSVP Keyboard<sup>TM</sup> potentially could be used by people with total LIS, and may be a good option for those with classical or incomplete LIS if other communication methods prove ineffective or overly fatiguing.

Since the RSVP Keyboard<sup>TM</sup> BCI system relies on P300 signals acquired via EEG, each user must be fitted with an EEG cap connected to a laptop computer, which processes the brain signals and displays the user interface for the RSVP Keyboard<sup>TM</sup> (created and displayed using MATLAB R2012b<sup>®</sup>). During system calibration and typing mode, the user watches a series of symbols presented on the laptop screen, one at a time, for a duration of 200 to 400 ms each. Symbols include the 26 letters of the English alphabet, plus symbols for backspace and space, and are presented in large (55 mm), white characters on a black screen. When the desired letter appears, a P300 response is elicited, and the RSVP Keyboard<sup>TM</sup> captures and analyses this response as a keystroke [33,34].

We describe the development of the RSVP BCI screening protocol for people with LIS, designed as a brief, repeatable tool for the identification of skills needed for use of the RSVP Keyboard<sup>TM</sup> BCI system. We report on the results obtained by administering the screening protocol to people with LIS and healthy control participants.

#### Method

#### **Development of the RSVP BCI screening protocol**

**Building consensus for the 'must haves'**—The foundational requirements of the RSVP BCI screening protocol must be sensitive to patient characteristics and environmental demands. Our goal is to develop a tool that is quick to administer, portable and adaptable to the physical and endurance capacities of this population, and unobtrusive in the patient's environment. Since people with LIS present with severe speech and physical impairments, the protocol must allow for responses that rely on eye movements or any consistent and reliable yes/no signal. The acceptance of these response modes ensures the participation of

patients who cannot use standardized instruments and conventional response methods. To keep participant fatigue at a minimum, the protocol should require no more than one hour to administer. Finally, the screening should require minimal equipment and materials, and should be easy to administer in a patient's residence or in medical settings.

Identifying requisite skills for use of the RSVP Keyboard<sup>™</sup>—The first step in the development of the screening protocol was to identify the requisite skills for use of the RSVP Keyboard<sup>TM</sup>. An expert clinical team familiar with LIS, including three speech and language therapists, a board-certified neurologist and neurophysiologist, a special educator with certification in vision impairments, a neurobehavioral optometrist, and a physical therapist, each identified a set of skills, from their respective disciplines, that were deemed necessary for BCI use. Since the purpose of this protocol was to determine the presence or absence of necessary skills, each team member was instructed to only propose skills that were requisite and mandatory for BCI use, and to keep in mind the question, 'Is the skill present?', not 'How capable is the person with this skill?' [31]. The initial proposed skill list was put through a systematic review of the BCI assessment literature (refer to our initial discussion of assessment for people with LIS) to confirm that skills previously evaluated for people with LIS were considered for this screening protocol. Often, the team discussed how to reduce the required skill set to maintain a short administration time, limited equipment needs, and modified response modes. A consensus process was implemented and agreement was achieved.

With careful and repeated clinical task analysis of the RSVP Keyboard<sup>™</sup> BCI by the multidisciplinary team, and observing people both with and without disabilities as they used the system, the following skills were included in the screening protocol: adequate hearing and auditory comprehension for following instructions, adequate vision, visual perception and sustained visual attention for seeing letters on the screen and attending to the task, and adequate literacy and spelling skills for recognizing letters and words and composing written messages. Vigilance and working memory are necessary for the user to sustain attention to the task as well as to track symbol selections. Potential interference from pain and medications must be identified, and motor function should be assessed for unintentional muscle movements or sub-optimal positioning which may affect EEG signal acquisition.

Selection and modification of protocol components—The final RSVP BCI screening protocol includes a compilation of structured interview questions, subtests from existing standardized instruments well known to practitioners of cognitive-communication assessment, and original subtests designed by the authors to screen skills that are not adequately addressed elsewhere. Subtests from existing instruments were selected based on their relevance to the requisite skills for using the RSVP Keyboard<sup>™</sup>. Although administering only subtests of an assessment instrument affects its validity, for the purposes of this screening protocol we are not interested in obtaining a validated score. Our intent is simply to determine the presence or absence of a potential user's skills quickly and efficiently, without the use of extensive testing that would be time-consuming and overly fatiguing for the target population. Modification of response modality affects validity as well, and we chose to use standard subtests with novel response modes in order to get an

initial picture of what each patient can do. Our goal is also to start a standardization of initial screening skills that should be examined in BCI end users. See the Appendix for a full list of questions and subtests included in the screening protocol.

**Strategies for expressive communication:** Because all screening items are modified to require only yes/no responses, it is imperative that the examiner is familiar with the patient's most reliable signal demonstration. Family members or care providers are queried about the reliability of the patient's signals for yes/no responses, and the examiner writes a description of the specific actions the patient uses to indicate 'yes' and 'no'.

Sensory abilities: To use the RSVP Keyboard<sup>™</sup>, a patient must demonstrate adequate hearing for following instructions and adequate vision to identify letters on the computer screen. In keeping with the established notion that the screening should require minimal equipment and be easy to administer in a patient's residence, it was determined that we would not perform a formal audiologic evaluation. Our goal is not to establish the presence of a hearing loss; rather, we are more interested in the conversational hearing skills a participant demonstrates on a daily basis. Therefore, we generated several questions about functional hearing in conversation, history of hearing loss and hearing aid use. These questions are directed to the patient, family member and/or care provider. Similar questions address visual issues, including whether the patient can see well enough to read, history of use of corrective lenses, and potential visual problems that may affect AAC use, such as diplopia, hemianopsia, cataracts, or macular degeneration [39].

Pain has been found to interfere with attention, particularly during complex tasks [40,41], and has led to increased reaction times [42]. To determine the presence or absence of pain interference that may affect performance with the RSVP Keyboard<sup>TM</sup>, the screening protocol includes five items selected from the PROMIS-Pain Interference Bank (PROMIS-PI) [43]. Administering the entire PROMIS-PI would greatly extend the length of the screening protocol, and the majority of its questions were deemed irrelevant to potential performance with the RSVP Keyboard<sup>TM</sup>. The five selected questions focus on how pain affects concentration, memory, the ability to take in new information, feelings of discouragement, and the ability to think about things other than the pain, all of which may affect a patient's ability to learn and perform a complicated skill such as spelling with the RSVP Keyboard<sup>TM</sup>. On each item, the patient is asked to rank his or her response on a scale from one to five. For patients with LIS, the response scale is presented visually, and the examiner scans through the scale, slowly reading each number aloud and watching for the patient's 'yes' signal to confirm the desired response.

**Medications:** Certain types of medications, including sedative, anti-depressant, antiepileptic, psychiatric, and pain medications, may affect a patient's EEG, P300 signals and cognition [44,45]. Patients (or their family members or care providers) are asked to list any current medications that fall into these categories.

<u>Motor function and positioning</u>: Patients with LIS spend many hours each day in the same position, at times resulting in discomfort or spasticity. Underlying diagnoses such as cerebral palsy may also cause uncontrolled muscle movements and spasticity, which can

have a detrimental effect on EEG signal acquisition [46]. The screening protocol requires the input of a physical therapist to provide a narrative description of the patient's motor function, including identification of unintentional muscle movements. The physical therapist makes recommendations for patient seating and computer positioning to promote energy conservation, comfort, adequate muscle relaxation and optimal viewing of RSVP stimuli for successful use of the RSVP Keyboard<sup>TM</sup>.

**Visual perception:** When typing with the RSVP Keyboard<sup>TM</sup>, the user must identify symbols presented in the centre of the screen. Once selected, the chosen symbol then appears in the upper left quadrant of the screen. Depending on the length of the word or phrase being typed, the user must accurately perceive letters and symbols in the upper left, upper centre and upper right areas of the screen. There are tests of visual perception available commercially. However, these tests are more comprehensive than required for the screening protocol, as we aim only to determine whether the individual has the requisite visual perceptual skills to learn to use the RSVP Keyboard<sup>TM</sup> for communication. As such, the authors chose to create the novel 'Four Corners' task to determine the presence or absence of the visual perception skills required for successful use of the RSVP Keyboard<sup>TM</sup>. This computer-based task was created and run using E-Prime 2.0<sup>®</sup>, a software suite for computerized experimental design and presentation. The task is administered on a laptop computer positioned in front of the patient at a distance of 50 to 100 cm, according to ergonomic standards recommended by the U.S. Occupational Safety & Health Administration [47]. During the subtest, the monitor displays a target letter in the centre for three seconds, followed by a red fixation cross for one second and then a screen with four letters, one in each quadrant, for three seconds. All letters are 55 mm tall, replicating letter size in the RSVP Keyboard<sup>TM</sup>. The patient is asked to identify if the target letter appeared in the group of four letters, and a yes/no response is elicited. This subtest is sensitive to hemispatial neglect or hemianopsia if the patient misses multiple items in the same quadrant(s) of the screen.

**Sustained visual attention:** Using the RSVP Keyboard<sup>TM</sup> involves looking continuously at visual stimuli for extended periods of time, requiring sound visual attention skills. Again, although there are commercially available assessments of sustained visual attention, it is our intent to determine the presence or absence of only the task-specific, requisite skills for successful RSVP Keyboard<sup>TM</sup> use, to require minimal motor responses, and to minimize the length of the screening protocol. As such, the authors designed a second computer-based subtest in E-Prime 2.0<sup>®</sup> in order to determine if the patient has sustained visual attention required for the RSVP Keyboard<sup>TM</sup>. This novel 'Sustained Visual Attention' task is a simulation of the way symbols are actually presented in the RSVP Keyboard<sup>TM</sup>. At the beginning of each trial, a target letter is displayed in the centre of the monitor for three seconds, followed by a red fixation cross for one second. A series of letters then flashes quickly on the screen, and the patient is asked whether the target letter appeared in the letter series, again eliciting a yes/no response. (The patient is not being monitored by EEG during this subtest.) All letters are 55 mm in size. Letters are initially presented in series of 10, at a rate of one every 400ms, mimicking the RSVP Keyboard<sup>TM</sup>.

**Memory & speed of information processing:** An RSVP Keyboard<sup>TM</sup> user must maintain information in working memory to effectively communicate using this technology. As letters flash rapidly on a screen, the user must consider questions such as, 'Am I looking for an 'M' or an 'N'?' 'What is the word I am trying to spell?' 'What letter should come next?' To this end, patients and their care providers or family members are asked to describe any concerns they have about the patient's everyday memory or attention. The examiner notes any distracting conditions observed during screening protocol administration, as this can provide insight into the patient's divided attention skills.

The 'Sustained Visual Attention Task' described above also addresses the presence or absence of working memory and speed of information processing difficulties, as the patient must keep the target letter in mind as other letters are displayed on the screen. The subtest can be modified in two potential ways. First, to decrease the working memory/sustained attention load, the series length can be reduced from 10 to five symbols. Second, to reduce the speed of information processing load, symbol presentation time can be increased from 400ms to one second. This subtest indicates whether a patient is able to attend to a series of quickly flashing symbols and identify a target.

Auditory comprehension: In order to learn to use the RSVP Keyboard<sup>TM</sup>, the patient must demonstrate adequate comprehension of spoken verbal instructions of the task. Continuing to focus on a screening tool that asks, 'Is the skill present for BCI use?', not 'How capable is the person with this skill?', we chose to determine the presence or absence of auditory comprehension skills with subtests from the JFK Coma Recovery Scale-Revised (CRS-R) [48] and the Western Aphasia Battery-Revised (WAB-R) [49]. The Object-Related Eye Movement Commands, Non-Object-Related Eye Movement Commands, and Visually-Based Situational Orientation subtests of the CRS-R are administered to determine if the patient comprehends commands and yes/no questions related to the immediate environment. Since the CRS-R was designed for use with patients with disorders of consciousness, these subtests already accommodate responses by eye movements and yes/no signals. The Auditory Verbal Comprehension: Yes/No Questions subtest of the WAB-R, a very common language assessment tool in the field of speech and language therapy, is included to further explore auditory comprehension with questions related to the patient's life (e.g. name and city of residence), the immediate environment, and general knowledge. No modification was necessary for this subtest, as it requires only yes/no responses.

**Reading comprehension and literacy:** To successfully use the RSVP Keyboard<sup>™</sup> BCI system for communication, a patient must demonstrate the ability to read what has been spelled at a minimum of the word level. The patient is asked about her past literacy skills and whether she is able to read words currently. Subtests for this initial determination of reading comprehension and literacy skills include the Object-to-Picture Matching and Picture-to-Word Matching subtests of the Functional Linguistic Communication Inventory (FLCI) [50]. The FLCI is a popular screening instrument used with adults who present with language impairments. Both of these subtests examine pre-literacy skills, giving information on the patient's ability to use symbol-based systems, which may be a viable alternative if he is unable to use a text-based system. Since the original subtests required a pointing response,

modifications were made to permit eye gaze responses. For the RSVP BCI screening protocol, the subtests are administered with response options presented on an E-tran (eye transfer) board [51], a clear Plexiglas frame with written options on cards placed at the sides and corners, as seen in figure 2. The board is held between the examiner and the patient, so that the examiner can see the patient's eyes through the centre hole and identify the direction of the patient's gaze. Words in the Picture-to-Word Matching subtest are presented in the same font and size used in the RSVP Keyboard<sup>TM</sup>.

**Spelling:** Word-level spelling skills are necessary for composing messages on the current, letter-based version of the RSVP Keyboard<sup>™</sup> BCI. The ability to identify the first letter of a desired word may be useful in future versions, which will incorporate word prediction and completion functions. Since existing spelling assessment tools require either written or spoken responses, two original tasks were created to screen spelling in a manner consistent with the communication abilities of people with LIS. The 'First Letter of Word Identification' subtest borrows words and pictures from the Boston Naming Test (BNT) [52]. The patient is shown a picture of a familiar object and asked to indicate the first letter of the word for that object. Response options are again presented using an E-tran board, with four letter choices for each item. The second spelling task, 'Spelling to Dictation', requires the patient to spell a series of four-letter words spoken aloud by the examiner. For each item, a set of eight letters is arranged along the sides of the E-tran board, and the patient spells by eye pointing to each letter in the word.

**Equipment needed**—Administration of the RSVP BCI screening protocol requires the following materials, which are easily transportable: a laptop computer on a lightweight floor-stand mount, a set of small handheld objects, and an E-tran board with picture, word, and letter stimulus cards.

**Obtaining consensus from the clinical team**—The preliminary screening protocol was reviewed by the expert clinical team. Refinement and revision of the protocol followed, based on input from this group of experts. The protocol was then administered to a team member with LIS, whose feedback was incorporated. Recommendations from the group included omitting several instruments that had initially been considered for inclusion, such as visual fixation and visual pursuit tasks and the Rhinne bedside hearing test. These items were rejected because they lacked reliability or did not represent skills that would be needed for completing the RSVP Keyboard<sup>™</sup> task. The clinical team also recommended the addition of questions related to pain interference, medications, and motor function, which were not included in the preliminary draft. After 11 iterations, the RSVP BCI screening protocol was finalized to consist of 10 subtests and 22 questions to patients and care-providers.

#### Administration of the RSVP BCI screening protocol

Eighteen participants were recruited from the greater Portland, Oregon, metropolitan area, including 12 people with LIS and a convenience sample of six healthy controls. Recruitment of people with LIS was accomplished through community advocacy groups (the ALS Center of Oregon and the ALS Association Oregon and SW Washington Chapter) and the

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outpatient Neurology and AAC Clinics at Oregon Health & Science University. Participants with LIS met the following inclusion criteria: (1) diagnosed with an acquired neuromuscular or neurodevelopmental disorder; (2) between 18 and 80 years of age; (3) capable of participating in one- to three-hour experimental interactions; (4) literate in English and capable of spelling words; (5) normal or corrected vision and hearing; (6) speech that is understood less than 25% of the time and/or severely reduced hand function for writing and/or typing; and (7) willing to be videotaped for research purposes. The screening protocol was administered to individuals with LIS in their residences and to healthy controls in a quiet office environment.

The 12 with LIS presented with the following conditions: 10 had incomplete LIS and two had classical LIS. Six participants presented with amyotrophic lateral sclerosis (ALS), one with history of cerebrovascular accident (CVA), one with severe spastic-athetoid cerebral palsy (CP), one with spastic quadriplegia secondary to arterial venous malformation (AVM), one with Duchenne muscular dystrophy (DMD), one with spinocerebellar ataxia (SCA), and one with progressive supranuclear palsy (PSP). Three participants with LIS were women, and two came from minority groups.

## Results

#### Administration time

All 12 participants with LIS were able to complete the screening protocol in a single session lasting one hour or less. Clinicians and participants reported that they felt the administration time was appropriate for the abilities and endurance of this population. Administration time for healthy controls averaged approximately 20 minutes.

### Screening protocol results

**Response methods and overall performance**—All participants with LIS could reliably indicate yes/no responses, using methods including speech, eye movements, blinking, or movements of the head, feet, or hands. The six healthy controls and nine of 12 participants with LIS scored 100% on all RSVP BCI screening tasks. The remaining three participants with LIS missed items on only a single task.

**Sensory abilities**—All participants had hearing that was within functional limits for normal conversation and administration of the screening protocol. All could see well enough to read and to identify pictures and objects. Two participants with LIS reported experiencing diplopia. One of these participants had prescription lenses to correct the diplopia, but also presented with reduced vertical eye movement, which affected his field of vision. However, he was able to see all areas of the computer screen during the Four Corners subtest.

**Pain interference**—Six of 12 participants with LIS reported problems with pain, though none reported that pain interfered with memory, concentration, or the ability to process new information. Two participants with LIS stated that their pain 'sometimes' or 'rarely' made them feel discouraged, and one stated that his pain was 'rarely' so severe that he could think of nothing else.

**Memory and attention**—Two participants with LIS (or their care providers) reported mild difficulties with memory and/or attention. No other challenges were reported for either control or LIS group.

**Motor function and positioning**—All 12 participants with LIS used a wheelchair for mobility. Eleven completed the screening protocol while in a seated position, and one was assessed while lying in bed. The materials used in the protocol proved to be easily adjustable for use with participants in a variety of positions. Two participants with LIS (both with spasticity due to either CP or AVM) demonstrated frequent, uncontrolled movements of the facial and respiratory muscles, which could potentially interfere with accurate EEG signal acquisition when using the RSVP Keyboard<sup>TM</sup>.

## Discussion

The RSVP BCI screening protocol is a tool that helps to identify skills needed for use of a specific brain-computer interface, and may serve as a model for similar tools to screen skills for other BCI systems. The consistent performance of the majority of participants with LIS on the RSVP BCI screening protocol indicates that screening tasks were well chosen and modified to obtain accurate responses by people with LIS, and confirms earlier reports showing the retention of basic cognitive abilities in people with LIS.

Use of the RSVP BCI screening protocol is possible in the home environment with people with LIS resulting from a variety of diagnoses. The protocol requires only a basic knowledge of screening techniques, and can thus be administered by researchers from a variety of clinical professions. Administration time involves a single session of approximately one hour, and varies depending on the response time, yes/no communication method, and fatigability of individual participants. Although a shorter administration time would be preferable, response modes and the management of screening materials (i.e. setup of laptop for computer-based tasks and arrangement of words, letters and pictures on an E-tran board) make it difficult to reduce administration time. The examiners and participants agreed that the screening time was reasonable for the target population.

The RSVP BCI screening protocol is an attempt to establish clinical observation of a set of cognitive-communication skills that are necessary for this class of new assistive technologies. The protocol is not a valid assessment tool for determining if a BCI is appropriate for an individual with LIS. Rather, it is a screening protocol useful for identifying whether a person has the requisite skills to use the RSVP Keyboard<sup>TM</sup> BCI. Results of the screening may provide researchers/practitioners with a valuable understanding of the end users skills and limitations when trialing the RSVP Keyboard<sup>TM</sup> BCI, leading to customization of the system to meet each user's individualized needs. This has significant implications for practice. For example, if, through screening, an end user is identified as having a visual field deficit in a certain quadrant, the BCI user interface could be modified to allow for presentation of visual stimulus in their preferred visual field. In place of current practice of trialing a BCI system with no objective data on why a user is not successful, the RSVP BCI screening protocol can be administered pro-actively to describe skills and possibly inform system modifications for enhanced performance. Consequently, rather than

a determination of 'this person cannot successfully communicate using BCI technology', there is now an outcome which has effectively identified and addressed an access barrier.

We must emphasize that the protocol cannot identify who can or cannot use the system, only whether they have requisite skills for system trials. Other BCI systems, such as the P300 Speller [36] or the intendiX® SPELLER [38], may require examination of different cognitive, motor, language and sensory skills since they do not rely on a rapid serial visual presentation of letters. It is the responsibility of all clinical researchers who are designing BCI systems to consider the skills that are needed by potential users, and to determine a way to evaluate those skills as one outcome measure for successful research and development. We propose the set of skills needed for the RSVP Keyboard. This protocol can serve as a model upon which to base additional screenings for other BCI systems user interfaces and should be the focus of future research. We recommend the standardization and adoption of a skill-based screening tool for BCI clinical research. Screening can improve outcomes, to better describe those individuals who demonstrate initial skills for success and to begin to understand the underlying cognitive-communication requirements across end users, and across BCI systems.

#### Acknowledgments

We wish to acknowledge the contribution of the Cognitive Systems Laboratory at Northeastern University, Boston, Massachusetts, as well as the time commitments of participants with functional LIS. We also wish to thank Meghan Miller for programming the Four Corners and RSVP subtests in E-Prime 2.0®. This research was supported by NIH Grant #1R01DC009834. Any opinions, findings, conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the NIH.

This study was supported by a grant from the National Institutes of Health #1RO1DC009834-01.

## Appendix

Skill	Questions or Subtests
Communication	<ul> <li>To care provider:</li> <li>1 'Does the patient have reliable yes/no signals?'</li> <li>2 'How does the patient signal 'yes'?'</li> <li>3 'How does the patient signal 'no'?'</li> </ul>
Hearing	To care provider: 1 'Does the patient have a hearing loss?' 2 'Does the patient wear a hearing aid?' 3 (If 'yes' to 2) 'In the right ear, left ear, or both?'
	To patient: 4 'Can you hear me?' 5 'Can you hear out of your right ear?' 6 'Can you hear out of your left ear?'

Questions and subtests used in the RSVP BCI screening protocol

Skill	Questions or Subtests
Vision	To patient:
	1 'Do you wear glasses?'
	2 (If 'yes' to 1) 'Is this a recent prescription?'
	3 'Can you see well enough to read?'
	4 'Do you have any other visual problem such as visual field cut, double vision, astigmatism, colour blindness, light sensitivity, cataracts, or macular degeneration?'
Pain interference	Items 1, 8, 29, 32, and 49 from the PROMIS-PI [43].
Medications	To patient or care provider:
	1 'Are you taking any sedative, anti-depressant, anti-epileptic, psychiatric, or pain medications?' List medications, if applicable.
Motor function and positioning	Physical therapist describes patient's motor function (especially any uncontrolled movements) and makes recommendations for optimal patient and computer positioning during BCI use.
Visual perception	Four Corners subtest (described above).
Sustained visual attention	Sustained Visual Attention subtest (described above).
Memory & attention	To care provider:
	1 'Are there any concerns about the participant's memory or attention?'
	Working memory assessed during Four Corners and Sustained Visual Attention subtests.
	Examiner describes any distractors observed during administration.
Auditory comprehension	Object-Related Eye Movement Commands, Non-Object Related Eye Movement Commands, and Visually based Situational Orientation subtests (CRS-R) [48].
	Auditory Verbal Comprehension: Yes/No Questions subtest (WAB-R) [49].
Reading comprehension and	To patient:
literacy	1 'Are you able to read words?'
	2 'Were you able to read words in the past?'
	Object-to-Picture Matching and Picture-to-Word Matching subtests (FLCI) [50].
Spelling	First Letter of Word Identification subtest (words and pictures borrowed from BN [52] : BED, TREE, PENCIL, HOUSE, WHISTLE, SCISSORS, COMB, FLOWE SAW, TOOTHBRUSH). Spelling to Dictation subtest (described above; words: STOP, BALL, PLUM, WANT, CAKE, FISH, LIFE, SLED, DARK, COME).

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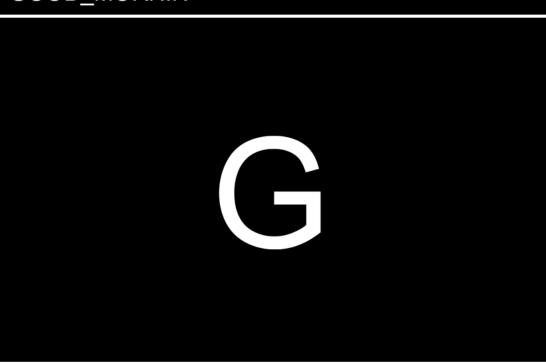
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## Implications for Rehabilitation

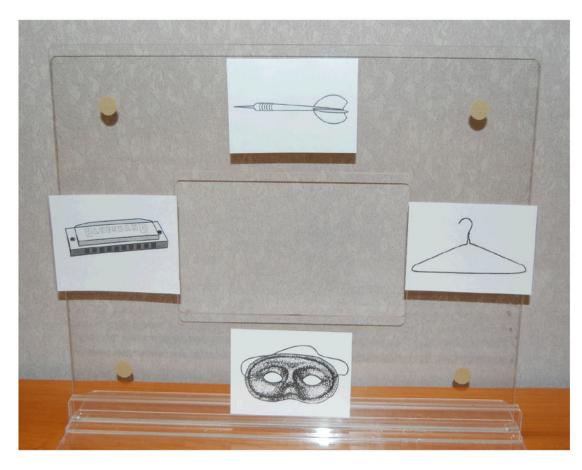
- People with locked-in syndrome must have certain sensory, motor, cognitive, and communication skills to successfully use a brain-computer interface (BCI) for communication.
- A screening profile would be useful in identifying potentially suitable candidates for BCI.

# GOOD\_MORNIN



#### Figure 1.

Sample RSVP Keyboard<sup>™</sup> display. Large letters are displayed in the centre of the screen following a rapid serial visual presentation (RSVP) protocol, and previously typed characters appear at the top of the screen. Font, size, color, and location of RSVP or typed string can be adjusted according to individual users' needs and preferences.



#### Figure 2.

E-tran board with response options for Object-to-Picture Matching subtest.