A revised sensory/cognitive/communication screen for use with communication BCI study participants

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Background

Original BCI Sensory/Cognitive/Communication Screen developed in 2012 [1]

- Designed to assess requisite skills for RSVP Keyboard™ BCI
- Required only yes/no responses and eye movements (suitable for use with people with incomplete and classic LIS)
- Successfully administered to 12 participants with severe speech and physical impairment

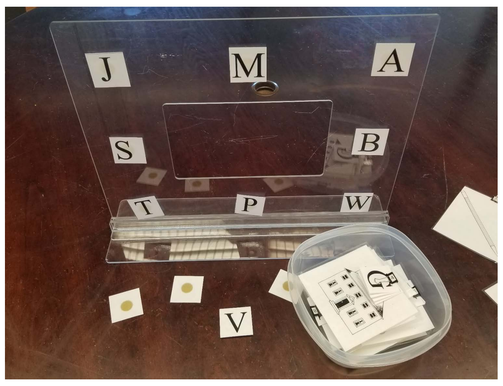
Project Goals

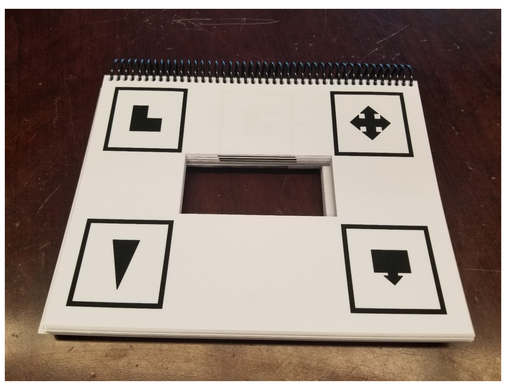
Goals for revised screen:

1. Simplify setup and administration
2. Obtain more complete background information from caregivers
3. Reduce potential for examiner bias
4. Adapt for skills relevant to a different BCI interface
5. Include informed consent procedures

Goal 1: Simplify setup and administration

Problem: E-TRAN board with Velcro-attached stimuli was cumbersome and time-consuming.





Solution: Flipbook with one screening item printed on each page and a hole for viewing eye movements.

Goal 2: Obtain more complete background information from caregivers

Problem: Caregiver questions prolonged screening visits. Caregivers may have felt uncomfortable giving thorough answers about some topics (e.g. cognition) in front of participants.

Solution: Revised screen includes a caregiver pre-screen, completed via telephone, with questions on communication, motor, vision, hearing, and cognitive abilities.

Pre-screen: Communication

9. How does participant communicate? Please include any and all communication methods used.

_____

_____

10. Does participant have reliable signals for "yes" and "no"?
☐ 1 Yes
☐ 2 No

11. How does participant signal "yes"? (Please list/describe all signals):

_____

12. How does participant signal "no"? (Please list/describe all signals):

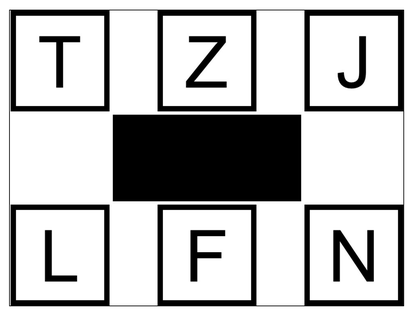
_____

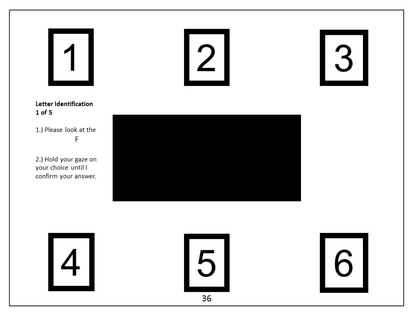
13. Do you have any concerns about participant's ability to understand spoken or written words?
☐ 1 Yes* If yes, please describe: _____
☐ 2 No

Goal 3: Reduce potential for examiner bias

Problem: Examiner knew correct answer locations on E-TRAN board. When a participant's eye movements were difficult to interpret, it was tempting to point to the correct answer to confirm a response, potentially affecting the results.

Solution: Flipbook shows only number-coded boxes on examiner pages. Examiner records the number of a participant's response, then compares it to an answer key for scoring.

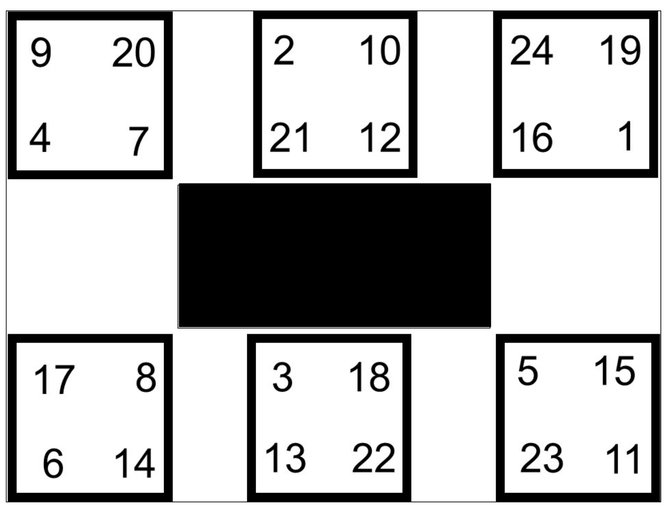




Goal 4: Adapt for skills relevant to a different BCI interface

Problem: Original screen assessed requisite skills for the RSVP Keyboard™ BCI. Different skills are relevant to using a BCI with the Shuffle Speller interface.

Solution: Revision began with task analysis to identify skills and characteristics relevant to use of the Shuffle Speller BCI. Visual skills including fixation, pursuit, saccades, visual field, acuity, and visual perception are screened with items based on standardized assessments, modified for yes/no and eye movement responses. Subsequent items address pain interference, current medications, motor function, and positioning concerns. A modified Trail Making Test [2] screens cognition, followed by novel tasks addressing concepts of print, letter identification, copy-spelling, word completion, and error awareness.



Modified Trail Making Test instructions:
Please use your eyes to show me the correct number sequence from 1 to 24. Please hold your gaze on your choice until I confirm your answer.

Goal 5: Include informed consent procedures

Problem: Previously, we obtained informed consent before screening, assuming participants had the necessary hearing and auditory comprehension skills. (An authorized research representative signed on the participant's behalf.) We wished to revise our procedures to reduce the potential for doubt about a participant's ability to provide informed consent.

Solution: Revised screen includes informed consent procedures based on Vansteensel et al [3]. After a hearing screening, participants answer yes/no situational orientation and auditory comprehension questions. Respondents with a passing score of ≥19/20 on these sections are read the study consent form and asked 10 yes/no questions related to its content.

Informed Consent

40. Total score for 36-38: ____/20

If score is ≥19, continue to item 40. If score is ≤18, participant may be decisionally impaired. Repeat any items on which the participant had one or more incorrect responses. Repeat all questions within any repeated item, and repeat each item only once. If the participant improves to ≥19 on the second administration, proceed to item 40. If not, participant is ineligible for the current study.

41. Consent Form: Yes/No Questions: ____/10

Read through consent form with participant before asking these questions. If a participant answers a question incorrectly, re-read the relevant section of the consent form and ask again.

1. Will the study take 3 to 6 months to complete?	Y	☐ Correct ☐ Incorrect
2. Will you come to our office at OHSU?	N	☐ Correct ☐ Incorrect
3. Does the study involve testing a new medication?	N	☐ Correct ☐ Incorrect
4. Does the study involve testing a new typing interface?	Y	☐ Correct ☐ Incorrect
5. Will you wear a headband to hold electrodes on your head?	Y	☐ Correct ☐ Incorrect
6. Will each data collection session last 5 hours?	N	☐ Correct ☐ Incorrect
7. Is there a risk of mild discomfort or eye strain?	Y	☐ Correct ☐ Incorrect
8. Will we make your personal data available to the public?	N	☐ Correct ☐ Incorrect
9. Will you receive a $1 gift card for each study visit?	N	☐ Correct ☐ Incorrect
10. Do you have the right to quit the study at any time?	Y	☐ Correct ☐ Incorrect

Pilot Testing Results

- 2 people with severe speech & physical impairments completed the revised screening procedure and provided feedback, using only yes/no responses and eye movements
- 1 caregiver completed the caregiver pre-screen via telephone
- Time required: 20 minutes for caregiver pre-screen phone call, 60 minutes for participant screen (not including informed consent)
- Informed consent times may vary depending on whether participants and their research representatives have read consent form in advance, what questions they have, etc.
- Screen was compact and easy to transport and administer in participants' homes

Significance

- Revised screening tool:
  - Allows for thorough description of the skills and characteristics of BCI study participants
  - Provides a method for obtaining informed consent from individuals with SSPI
  - May reveal sensory/cognitive/communication barriers to successful BCI use, leading to identification of modifications and supports to help overcome such barriers
  - May be a model for the development of screening tools tailored to other BCI systems.
- More detailed participant description will lead to better sharing and comparison of results within the field

Acknowledgements:
This work was supported by RERC NIDILRR grant # 90RE5017 and NIH grant # 2RO1DC009834-06A1 (Dr. Melanie Fried-Oken, P.I.)

References:
1. Fried-Oken, M., Mooney, A., Peters, B., & Oken, B. (2015). A clinical screening protocol for the RSVP keyboard brain–computer interface. Disability and Rehabilitation: Assistive Technology, 10(1), 11-18.
2. Trail Making Test, Bowie & Harvey, 2006.
3. Vansteensel, M. J., Pels, E. G., Bleichner, M. G., Branco, M. P., Denison, T., Freudenburg, Z. V., ... & Van Rijen, P. C. (2016). Fully implanted brain–computer interface in a locked-in patient with ALS. New England Journal of Medicine, 375(21), 2060-2066.