# STUDY AIMS

**From ALSA grant proposal**

The primary aim is to build upon the newly established ALS telemedicine program at Penn State Hershey Medical Center by incorporating a brain-computer interface (BCI) communication module in order to evaluate utility of in-home telemedicine visits by the clinical team for patients who possess limited verbal communication. This aim will be accomplished in three stages.

1. A low-cost telemedicine video interface will be used to train the patient and caregiver in the application and operation of a virtual keyboard based on the P300 evoked brain potential. The patient will use the telemedicine interface to transmit BCI messages back to the research team on a weekly basis over a cloud-based file sharing platform that exists within the secure Penn State Hershey computing infrastructure. Through that interface, the team will regularly adjust system parameters to improve BCI performance.
2. When the patient reaches proficiency with this system, they will communicate through the telemedicine portal in order to directly and autonomously interact with clinicians during a virtual clinical visit. This interaction will serve as the primary endpoint of the study.
3. Assessment of outcomes will be determined. A survey will be administered to the patient and caregiver, and to members of the ALS care team, to assess their opinions of the telemedicine and assistive communication interfaces (see Statistical Methods below for details). Other qualitative measures of device accuracy and communication speed will also be reported.

The secondary aim of this study is monitor the long-term change in communication quality through the telemedicine interface. Through a combination of eye tracking, accuracy, and time to complete BCI tasks, we will be able to monitor improvements in user skill with the device. Although not a primary goal of the study, this type of longitudinal data collected from patients who opt to retain the BCI system will contain critical information about the learning and stability associated with such a device

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| **REDCap Data Collection Instruments** | | |
| **REDCap Instrument** | **Abb.** | **Data** |
| Screening | S | Personal identifiers, inclusion/exclusion criteria, screening questionnaire. |
| Patient Information | PI | Personal information from initial study visit, ALSFRS-R, ECAS, ALSSQOL-20 (before and after), HOSU – History of support use, ATDPA – Assistive technology device predisposition assessment (before and after), Patient and Caregiver consent forms. |
| Post Session Researcher Log | RL | Filled out by researcher during/after the videoconferencing session. Includes session data – a zip file containing eye tracker calibration file, impedance file, P300 run data, classifiers and filters, prepared text library. |
| Post-Session Participant Log | PL | *Survey* – triggered when the date on RL is input. |
| Clinical Interaction | CI | Filled out by the researcher during/after the clinical interaction. |
| Participant Assessment | PA | *Survey* – triggered when date on CI is input. |
| Nurse Assessment | NA | Filled out by nurse clinician after interaction. |
| Completion Data | CD | Information about the study endpoint and the optional extension. Includes space to track researcher involvement that occurs during the extension and a place to put data. |
| Extension Check | EC | *Survey* – triggered every month by automated scheduler. Checks how often the system has been used and if participants wish to continue using. |

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| **Analysis plan for Aim 1.1** | | |
| **Question** | **Data collection instrument** | **Analysis** |
| How many participant teams expressed interest and underwent screening? | S | Count |
| What were the reasons for study ineligibility? | S | Descriptive |
| How many participant teams took part in the study? | PI | Count |
| What were the demographics (age, gender, education, distance from clinic, date of symptom onset, region of symptom onset, family history of ALS, ALSFRS-R, ALSSQOL, ECAS)? | PI | Count / Mean (SD) |
| What assistive communication devices were used by patients and for how long? | RL (HOSU) | Descriptive |
| What was their satisfaction with current AAC? | RL (HOSU) | Mean (SD) |
| What is initial predisposition to the teleBCI as an AAC? | RL (ATDPA initial) | Count / Histogram |
| Did age, gender, mood, alertness, eye tracking accuracy and precision, ALSFRS, cognition etc. predict a strong P300 response? | PI, SD | Multiple regression |
| What was the length of each teleBCI session? | RL | Mean (SD) |
| What was the rate of log completion? | PL | Mean (SD) |
| What was the retention/dropout for the full length of the study? | CD | Count |
| What were the reasons for dropout? | CD | Descriptive |
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| **Analysis plan for Aim 1.2** | | |
| **Question** | **Data collection instrument** | **Analysis** |
| How many nurses were included in the study and how many interactions did they each have? | NA | Count |
| How long were these interactions? | CI | Mean (SD) |
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| **Analysis plan for Aim 1.3** | | |
| **Question** | **Data collection instrument** | **Analysis** |
| Were participant team assessments and nurse clinician assessments completed for each clinical interaction? | PA, NA | Count |
| Was teleBCI an improvement (efficacy and speed) over other no AAC or current AAC? | PA, NA | Chi-Squared test..Eric -- Kruskal wallis then Wilcoxon |
| How did the participant team and nurse perceive the efficacy, accuracy, and speed of the device? Did they differ? | PA, NA | Count, t-test / Wilcoxon rank sum |
| How did the patient perceive ease of use, ease of setup, and portability of the device? | PA | Count / Histogram |
| What was the patient’s comfort with the cap, electrodes, eye tracker, and P300 speller? | PA | Mean (SD) |
| What system accessories were used by the patient? | PA, NA | Count |
| Were these accessories perceived as helpful to the participant team and nurse? | PA, NA | Count, t-test / Wilcoxon |
| Broken down by task, was the time spent appropriate? | PA | Chi-Squared test |
| Broken down by task, what would the participant team change? | PA | Descriptive |

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| **Analysis plan for Aim 2** | | |
| **Question** | **Data collection instrument** | **Analysis** |
| Did average impedance change over sessions? | RL (impedance file) | Eric – Regression is not the best for this.  Repeated measures anova. Or  Signed rank test on pairwise timepoints then correct for multcomp |
| Did eye tracking accuracy and precision change over sessions? | RL (eye calib) | “” |
| Did the time to complete each task change over sessions? | RL (timestamp) | “” |
| Did the length of the session change over time? | RL (timestamp) | “” |
| Did quality of the evoked potential change over sessions? | RL (P300 data) | “” |
| Did the accuracy change over sessions? | RL (BCI data) | “” |
| Did the speed change over sessions? | RL (BCI data) | “” |
| Did changes in accuracy and speed yield a change in bit rate? | RL (BCI data) | “” |
| Did the patient rated quality of life change from the beginning to the end of the study? | PI | t-text / Wilcoxon |
| How did disposition towards BCI use change from the beginning to the end of the study? | RL (ATDPA initial and followup) | t-test / Wilcoxon |
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| **Analysis plan for Extension** | | |
| **Question** | **Data collection instrument** | **Analysis** |
| How many participants were recommended for the extension? | CD | Count |
| How many participants opted to extend their use of the system? | CD | Count |
| What factors predicted extension? | CD, PI, RL (HOSU, ATDPA), PA | Multiple logistic regression |
| How long did extensions last? | CD | Mean (SD) |
| What was the number of sessions per extension? | EC | Mean (SD) |
| Did others learn the role of the caregiver during this time? | EC | Descriptive |
| What was the average time spent during each session? | EC (timestamp) | Mean (SD) |
| Did bit rate improve during the extension? | EC (BCI data) | Regression |
| Which features were used during the extension? | EC | Descriptive |
| What were the reasons for terminating the extension? | CD | Descriptive |