Remote Neurobased Approach to Aphasia Therapy

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Study Protocol

Therapy will be administered to participants through a mobile application which all participants in the experimental group will use at home for two weeks. Before starting the use, pre-tests are conducted to determine the baseline scores of language function and communication using the Barcelona test and the Communicative Activity Log. In the introductory session, after the tests, the application is installed on the participant's own phone and the participant is given instructions and trained in how to use the application, before starting their individual use of it at home. The therapist will prescribe use of the application 2 times per day for 20 minutes. Support is made available during the two weeks, if the participant is having issues with the use of the application. Furthermore, all patients are informed that they are allowed to receive help from family members or others in using the application at home.

The participant is instructed to use the application two times every day for about twenty minutes, but although this was the recommended use, the participant is free to use the application when and for as long as they want. While using the app, the participant will, through the app, be informed when they have been practicing for twenty minutes, in order to limit their use to shorter but more frequent sessions. The practice consists of several different tasks that are connected to different contexts from everyday life. The tasks consist of matching visual objects, sounds, and short videos, as well as some written input of words. The tasks also ask participants to record their voice saying the name of the object and to listen to and evaluate their recording.

After two weeks, the participants will return and be given post-tests on the same measures as before the start of the treatment, i.e., clinical scales for assessing language function and communication. Additionally, they will complete two usability questionnaires (the System Usability Scale and the mHealth App Usability Questionnaire), and a few questions regarding risk assessment.

The control group will also receive the pre-tests on the first day and post-tests 14 days later. They will not receive any treatment in that period, and they are not instructed to do or not to do anything in particular while at home. This means that the control group participants will proceed with their daily life as normally. The usability questionnaires will only be administered to the experimental group, not to the control group.

Plan for Statistical Analysis

The analysis of the Barcelona test and the Communicative Activity Log (CAL) will consist primarily of within-group analyses with the Wilcoxon rank sum test, because of the low number of subjects. Additionally, linear mixed effects models will be used for the between-group analyses, with the Barcelona Test and the CAL score for each domain (patient, family, and therapist), respectively, as the dependent variable. The main independent variable will be the pre-/post-test (time) through binary coding, as well as the control versus the experimental group, including the interaction between the time variable and the group. The participant ID will be included as random intercept in the model, to account for differences between participants. The validity of the regression analysis will be evaluated by testing the residuals of the model for normality using the Shapiro-Wilk test for normality. Given the low number of subjects, the descriptive statistics will be reported with medians and quartiles, as with non-parametric tests.

A descriptive analysis will be made of the SUS and MAUQ usability questionnaires to determine the potential of a mobile application by drawing general conclusions from the use of this specific application. These will be analysed with computation of overall scores and examination of scores of different qualities of the application and use.

Further analysis will consist of descriptive statistics of the use of the application, e.g., amount of use, reaction times, and recording length, for participants in the experimental groups. The variables will be checked for normality with the Shapiro-Wilk test and depending on the results either means and standard deviation or medians and quartiles will be reported. The use measures will be analysed with t-tests or Wilcoxon rank sum tests to evaluate whether they changed over time with the use of the application.

An additional analysis will be made of the score differences for the Barcelona test of the experimental group, where the amount of use will be included in a linear regression model. With the difference in test score as the dependent variable, the independent variables included will be the total amount of use of the application. This analysis will evaluate whether the amount of use influenced the outcome of the treatment.