Changes in Neuroplasticity Following Intensive Rehabilitation of Aphasia and/or Apraxia of Speech

Interventional Study Protocol

NCT ID:

DATE: 2020-09-30

Interventional Study Protocol

1. STUDY IDENTIFICATION

Unique Protocol Identification Number: 2016/1651-31

Brief Title: Changes in Neuroplasticity Following Intensive Rehabilitation of Aphasia and/or Apraxia of Speech

Official Title: Evaluating the Effects of Intensive Speech and Language Rehabilitation Regarding Neuroplasticity, Speech, Language, Communication Skills and Quality of Life for People with Acquired Aphasia and/or Apraxia of Speech in the Chronic Phase

2. STUDY STATUS

Study Type: Interventional

Record Verification: September 2020

Overall Status: Recruiting

Study Start: February 2, 2017 [Actual]

Primary Completion: December 31, 2023 [Anticipated]

Study Completion: July 31, 2024 [Anticipated]

3. SPONSORS/COLLABORATORS

Sponsor: Karolinska Institutet

Responsible Party: Principal Investigator

Investigator: Ellika Schalling [eschalling]

Official Title: Associate professor, Speech Language Pathologist

Affiliation: Karolinska Institutet

Collaborators: University of Malaga

4. OVERSIGHT

Studies a U.S. FDA-regulated Drug: No

Studies a U.S. FDA-regulated Device: No

Device Product Not Approved or Cleared by U.S. FDA: No

U.S Food and Drug Administration IND or IDE: No

HUMAN SUBJECTS REVIEW

Human subjects Protection Review Board Status: Submitted, approved

Board Approval Number: 2016/1651-31

Board Name: Swedish Ethical Review Authority
Board Affiliation: Etikprövningsmyndigheten
Phone: +46104750800 Email: registrator@etikprovning.se
Address: Box 2110, 750 02 Uppsala, Sweden
Data Monitoring: Yes
FDA Regulated Intervention: No
Section 801 Clinical Trial: No

5. STUDY DESCRIPTION

Brief Summary: The present study aims to investigate the short- and long-term effects of two weeks of intensive speech-language pathology intervention with additional physiotherapy, on aphasia and apraxia of speech (AOS) and their neural correlates in thirty persons with chronic stroke. Changes are studied following intensive treatment of aphasia and AOS with standardised speech-language testing and assement of communication as well as with voxel-based morphometry (VBM) analysis and resting state functional connectivity (rsFC).

Detailed Description: This study explores structural and functional brain changes in relation to effects on speech, language, communication and quality of life following an intensive speech-language program with additional physiotherapy for persons with chronic aphasia and/or apraxia of speech. The participants are consecutively recruited from a rehabilitation centre providing intensive treatment for chronic conditions following stroke or other neurological injuries. The speech-language pathologists (SLPs) involved in the rehabilitation programs perform the testing directly before and after intensive intervention with an additional follow up after 16 weeks (+-2) with testing of speech-language, communication and quality of life. The SLPs have more than five years of experience of working with aphasia and are specialised in working with intensive treatment, they have acquired in-depth knowledge on how to evaluate and treat aphasia and apraxia of speech in lectures and workshops. The test procedure is recorded with camcorder and voice recorder to provide the opportunity to access data retrospectively and to minimize bias by including an external SLP who makes a second blinded evaluation on randomized participants' performance in ASRS, BNT and CAT by studying the video and voice material. Structural and functional neuroplasticity is also investigated with voxel-based morphometry (VBM) analysis, resting state functional connectivity (rsFC) in domain-specific (language processing) and domain-general (executive and attention processing). This intensive neuro-rehabilitation program for speech and language impairments named Multimodal Intensive Rehabilitation for

Aphasia and Apraxia of Speech (MIRAA) is defined as an ICAP (Intensive Comprehensive Aphasia Program) with focus on both speech and language function and communicative activity and participation. The program is intensive: consisting of ten days of training (5 hours/day), with a minimum of three hours dedicated to speech and language rehabilitation with additional physical therapy. The program includes both individual treatment, group therapy and computer-based therapy. The therapy is individually set up after the participant's goals together with the team including SLPs, physiotherapists and a board-certified neurologist and/or specialist in rehabilitation medicine. The goals are set by the participants, family members and clinicians the first day of the program. The participant and their significant other are offered education with the aim to enhance the knowledge on communication, the key concepts of neuroplasticity and other functions and strategies important in everyday life. The treatment methods being used are evidence-based and/or widely used multimodal programs covering the need for extensive training programs targeting both impairment-based therapy and functional communication.

The specific questions are:

Does intensive intervention during ten days, with the MIRAA program result in any clinically significant improvements in speech and/or language functions and other cognitive skills for participants with chronic aphasia and/or apraxia of speech?

Does the intensive intervention have an effect on the quality of everyday life related to speech and language functions, activity and communicative participation for people with chronic aphasia and apraxia of speech?

Can functional and anatomical brain changes be detected following ten days of intensive speech and language intervention for these participants?

6. CONDITIONS AND KEYWORDS

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study:

1. Aphasia
2. Apraxia of Speech
3. Dysarthria

Keywords:

1. Intensive Aphasia Rehabilitation
2. Intensive Apraxia of Speech Rehabilitation
3. Neuroplasticity

7. STUDY DESIGN (INTERVENTIONAL)

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Single Group

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 30 [Anticipated]

8. ARMS, GROUPS, AND INTERVENTIONS

Arm 1: Arm Type: Experimental:

Arm Title: Multimodal Intensive Rehabilitation of Aphasia and Apraxia of Speech (MIRAA)

Arm description: A minimum of 3 hours speech-language training daily during 10 days.

Intervention 1: Intervention Type: Behavioural

Intervention Name: Multimodal Intensive Rehabilitation of Aphasia and Apraxia of Speech (MIRAA)

Intervention Description: Intensive Comprehensive Aphasia (ICAP) and Apraxia of Speech Program

Arm/Interventional Cross-Reference: Only one arm (arm 1, intervention 1).

9. OUTCOME MEASURES

Primary Outcome Measures

Outcome 1: Primary Outcome Measure:

Title: Comprehensive Aphasia Test (CAT) language battery, in pilot Swedish test A-ning.

Time Frame: Changes from baseline in Comprehensive Aphasia Test language battery scores at 2 and 18 weeks.

Description: Comprehension of spoken language: minimum score 0, maximum score 66; Comprehension of written langugage: minimum score 0, maximum score 62; Repetition: minimum score 0, maximum score 74; Naming: minimum score 0, maximum score no limit; Reading: minimum score 0, maximum score 70; Writing: minimum score 0, maximum score 76. Higher scores mean better outcome for language functions.

Outcome 2. Primary Outcome Measure:

Title: Rating scale for apraxia of speech (SkaFTA, Swedish version of ASRS)

Time Frame: Changes from baseline scores at 2 and 18 weeks.

Description: Minimum score 0, maximum score 52. Lower scores mean better outcome for speech functions.

Outcome 3. Primary Outcome Measure:

Title: Communication Outcome After Stroke (COAST)

Time Frame: Changes from baseline at scores 2 and 18 weeks.

Description: Minimum score 0, maximum score 100. Higher scores mean better outcome for communication.

Outcome 4. Primary Outcome Measures:

Title: Goal Attainment Scaling (GAS), International Classification of Functioning, Disability and Health (ICF). Aphasia adapted GAS scales for self-evaluation of communication functions, participation and activity.

Time Frame: Changes from baseline at week 18.

Description: Minimum score -2, maximum score +2. Higher scores can mean better outcome for quality of life.

Secondary Outcome Measures

Outcome 5. Secondary Outcome Measure:

Title: Barrow Neurological Institute Screening for Higher Cerebral Function (BNIS)

Time Frame: Changes from baseline at week 2.

Description: Minimum score 0, maximum score 50. Higher scores mean better outcome for cognition.

Outcome 6: Secondary Outcome Measure:

Title: Boston Naming Test (BNT)

Time Frame: Changes from baseline at week 2 and week 18.

Description: Minimum score 0, maximum score 60. Higher scores mean better outcome for naming ability.

Outcome 7. Secondary Outcome Measure:

Title: Test for Apraxia of Speech (TAX)

Time Frame: Changes from baseline at week 2 and week 18.

Description: Minimum score 0, maximum score 30. Lower scores mean better outcome for speech functions and non-verbal oral apraxia.

Outcome 8. Secondary Outcome Measure:

Title: Comprehensive Aphasia Test (CAT), subtest cognitive screening

Time Frame: Changes from baseline in Comprehensive Aphasia Test cognitive screening scores at 2 and 18 weeks.

Description: Minimum score 0, maximum score 38. Higher scores mean better outcome for cognitive functions.

10. ELIGIBILITY

Sex/Gender:

Sex: All

Gender Based: No

Minimum Age: 18

Unit of time: Years

Maximum Age: 75

Unit of time: Years

Accepts Healthy Volunteers: No

Eligibility Criteria:

Inclusion Criteria:

- Aphasia 7 months post stroke diagnosed by SLP
- Apraxia of Speech 7 months post stroke diagnosed by SLP

Exclusion Criteria:

- Dementia
- Severe visual impairment
- Severe hearing-impairment
- Metal implants (preventing fMRI)
- Claustrophobia (preventing fMRI)

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

Central Contact Person: Marika J Schütz, Ph.D student

Telephone: 0046737570430

Email: marika.schutz@ki.se

Study Officials: Ellika Schalling, Ph.D, SLP

Official's Role: Study Principal Investigator

Facility information:

Facility name: Karolinska Institutet, CLINTEC, Enheten för logopedi, F67, Karolinska University Hospital, Huddinge

City: Stockholm

ZIP/Postal Code: 141 86

Individual Site Status: Recruiting

Facility Contact:

Name: Marika Schütz

Degree: Ph.D student

Phone: 0046737570430

Email: marika.schutz@ki.se

12. INDIVIDUAL PARTICIPANT DATA (IPD) SHARING STATEMENT

Plan to Share IPD: Yes, all individual patient data (IPD) that underlie results in a publication.

Supporting Information:

Study Protocol

Informed Consent Form (ICF)

Analytic Code

Time Frame: 2020-2030

Access Criteria: Swedish National Data Service open source http://snd.gu.se/sv/dashboard/data-description/0a1f0ee0-454e-4d66-b43f-b235bfe821a6#publications