MIRAA – implementation of intensive rehabilitation of aphasia and/or apraxia of speech in Swedish healthcare

Interventional Study Protocol

NCT ID:

DATE: 2021-06-29

Interventional Study Protocol

1. STUDY IDENTIFICATION

Unique Protocol Identification Number: 2020-07182

Brief Title: MIRAA – implementation of intensive rehabilitation of aphasia and/or apraxia of speech in Swedish healthcare

Official Title: MIRAA – A national study on intensive rehabilitation of aphasia and apraxia of speech following stroke

2. STUDY STATUS

Study Type: Interventional

Record Verification: April 2021

Overall Status: Recruiting

Study Start: March 10, 2021 [Actual]

Primary Completion: December, 2022 [Anticipated]

Study Completion: December, 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

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: 2020-07182

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: Positive outcomes have been shown following intensive treatment of speech and/or language impairment post stroke, but how to design intensive treatment programs to achieve optimal recovery and neuroplasticity changes needs to be further researched. The purpose of the MIRAA (Multimodal Intensive Rehabilitation of Aphasia and Apraxia of Speech) project is to study feasibility of intensive intervention for acquired aphasia and apraxia of speech (AOS) after stroke in the regular Swedish healthcare according to the updated national guidelines from the Swedish National Board of Health and Welfare (Socialstyrelsen, 2018).

Detailed Description: According to the Swedish National Board of Health and Welfare's guidelines for stroke care, persons with aphasia shall be offered intensive rehabilitation by speech-language pathologists. The aphasia rehabilitation is however sparse and unevenly distributed over the country as reported by the Swedish Aphasia Foundation (Afasiförbundet, 2015). People with aphasia are seldom offered long-term treatment and intensive therapy is rarely offered (Blom Johansson, Carlsson et al., 2011; Palmquist, 2018). Intensive treatment is defined as at least 4h/week by the National Board of Health and Welfare, but higher intensity can be beneficial if tolerated by the patient. "It is not completely clear in which phase after stroke the intensive treatment should be offered but it seems more adequate in the sub-acute or chronic phase since a number people will not be able to participate in intensive treatment in the acute phase." (Socialstyrelsen, National guidelines for stroke care, p. 41–42).

Multimodal Intensive Rehabilitation of Aphasia and Apraxia of speech, MIRAA, is a modified ICAP intervention program developed in the applicant's research group. MIRAA consists of a selection of evidence-based and/or well-established methods for speech and language rehabilitation as well as computer training. The training is both individual and group based, including communication between participants to promote transfer to real-life situations. Rehabilitation is based on principles that have been shown to promote neuroplasticity changes, such as high training intensity and multiple repetitions of tasks, for

learning and relearning after brain injury. The intervention is goal-driven and individualized for high saliency, with focus on each participant's difficulties with language, speech and communication.

Speech and Language Pathologists (SLPs) all over Sweden working with aphasia and/or AOS following stroke are offered to participate in the study. At the time of recruitment, SLPs are invited to respond to a questionnaire about their current practice. SLPs accepting to participate are offered a 2-day workshop and recurring sessions containing introduction to and training in the MIRAA program as well as information about the logistics of the study.

The SLPs participating in the study recruit participants with aphasia/AOS from their waiting and offer them a six-week MIRAA rehabilitation program consisting of a combination of individual treatment and group session and computer-assisted/homework training, with the goal level of 60 hours. The content of the program is individually adapted to clinics and participants. Participation in the study is consecutively offered to all individuals with speech language impairment post stroke that meet the inclusion criteria.

Following administration of the MIRAA-program including pre- and post-testing, participating SLPs will complete a questionnaire on their experiences of delivering the intensive intervention and factors hindering and facilitating implementation. Participants with aphasia/AOS and their next of kin will also provide information about their experiences through questionnaires and semi structured interviews, focus groups interviews and participant observations.

All participants are tested pre- post and at follow-up by a speech and language pathologist. Behavioral tests consist of quantitative measurements of speech, language, communication, cognition and quality of life. Part of the testing (TAX and CAT informative speech) is video-recorded for analysis after testing.

Background data are obtained noting sex, age, handedness, education level, language history aphasia type and severity and AOS, time since onset, mental fatigue, social life, number of strokes and earlier intensive rehabilitation at the time of the first assessment.

A subgroup of participants and SLPs from five clinics distributed over varying types of clinics reflecting the diversity among the clinics (inpatient care, primary care) take part in semi-structured interviews based on interview guides combined with focus group interviews and participant observations during one day of the last week of the intensive program

focusing on facilitating and hindering factors for complying with an intensive intervention program like MIRAA.

A group consisting of SLPs not being able to participate in the study will form a focus group and discuss the specific factors hindering participation in the study in their respective settings.

The primary aim of this project is to explore the feasibility for national implementation of an intensive comprehensive intervention program for aphasia and AOS following stroke (MIRAA) in Swedish health care.

- What are facilitating or hindering factors for SLPs and their patients in the subacute and chronic phase post stroke with aphasia and/or AOS to comply with an intensive intervention program like MIRAA?
- How do participants, next of kin and SLPs experience intensive training in terms of effects and satisfaction with the program and with the implementation?

A secondary aim is to examine whether short-term and / or long-term effects on language, speech, communication and quality of life after intensive rehabilitation can be demonstrated.

- Can treatment effects regarding speech and/or language be detected when comparing the control group with the intervention group after six weeks of intensive intervention?
- Can treatment effects regarding communication and quality of life be detected when comparing the control group with the intervention group after six weeks of intensive intervention?
- Can long-term treatment effects on speech, language, communication and quality of life four months post intervention be detected?

Following clinics participate in the study:

- Aleris Rehab Station, Stockholm
- Dalen, Capio Rehab, Stockholm
- Farsta logopedmottagning, SLSO, Stockholm
- Fysrehab, Lidköping
- Logopedmottagningen Helsingborg och Ängelholm
- Logopedienheten, Södra Älvsborgs sjukhus, Borås
- Logopedkliniken, Danderyds sjukhus, Stockholm
- Logopedbyrån Dynamica AB, Stockholm, Gustavsberg och Södertälje
- Neurologimottagningen, Skånes universitetssjukhus, Lund

- Neurorehab, Vrinnevisjukhuset, Norrköping
- Närhälsan Gamlestadstorgets rehab, Göteborg
- Närhälsan Gibraltar rehabmottagning, Göteborg
- Närhälsan Angered, Rehabmottagning, Göteborg
- Närhälsan Frölunda Rehabmottagning, Göteborg
- Olivia Rehabilitering, Danderyd
- Rehab City Lidingö, Stockholms Läns sjukhusområde
- Rehabiliteringscentrum, region Jönköping
- Rehabenheten, Sjukhusen i väster, Göteborg och Kungälv
- VO Neurologi, Skånes universitetssjukhus, Lund
- Sävedalen rehabmottagning, Partille
- Vällingby logopedmottagning, SLSO Västra, Stockholm
- Specialistrehabiliteringsenheten, Uppsala
- Rehabenheten, Kliniken för medicin och geriatrik, Karlskoga

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

Keywords:

1. Intensive Rehabilitation
2. Neuroplasticity
3. Implementation in healthcare
4. Stroke guidelines
5. ICAP (Intensive Comprehensive Aphasia Program)
6. MIRAA (Multimodal Intensive Rehabilitation of Aphasia and Apraxia of Speech)

7. STUDY DESIGN (INTERVENTIONAL)

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallell

Model Description: Cluster randomized clinical trial with two parallel arms.

Number of Arms: 2

Masking: Investigator

Masking description: Block randomized sealed envelopes handled by external coordinator.

Allocation: Randomized

Enrollment: 70 participants with aphasia and/or AOS [Anticipated]

8. ARMS, GROUPS, AND INTERVENTIONS

Arm 1: Direct intervention **Arm Type:** Experimental

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

Arm description: Goal level 60 hours of intensive treatment during 6 weeks. Intensive treatment of aphasia and AOS in ICAP-format (MIRAA).

Arm 2: Control **Arm Type:** No Intervention

Arm Title: Waiting group

Arm description: No intervention during 6 weeks, testing directly before and after the waiting period. After the waiting period the participants receives the same intervention as the direct intervention arm.

9. OUTCOME MEASURES

Primary Outcome Measures

1. Evaluation of training, questionnaire to participating SLPs
Minimum score 0, maximum score 12. Higher scores mean better outcome on satisfaction with intensive training and effects on speech, language and functional communication. [Time Frame: Directly after intensive treatment]

2. Evaluation of training, questionnaire to participants
Minimum score 3, maximum score 12. Higher scores mean better outcome on satisfaction with intensive training and effects on speech, language and functional communication. [Time Frame: Directly after intensive treatment]

Secondary Outcome Measures

3. Comprehensive Aphasia Test (CAT)
Comprehensive Aphasia Test (CAT) language battery. Comprehension of spoken language: minimum score 0, maximum score 66; Comprehension of written language: 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 in language functions. [Time Frame: Changes from baseline in language battery scores at 6 and 16 (+-2) weeks.]

4. Boston Naming Test (BNT)
Minimum score 0, maximum score 60. Higher scores mean better outcome in naming ability. [Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

5. Rating scale for apraxia of speech (SkaFTA, Swedish version of ASRS)
Minimum score 0, maximum score 52. Lower scores mean better outcome in speech functions.
[Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

6. Protocol for Apraxia of Speech (TAX)
Minimum score 0, maximum score 30. Lower scores mean better outcome in speech functions and non-verbal oral apraxia. [Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

7. Comprehensive Aphasia Test (CAT), subtest cognitive screening
Minimum score 0, maximum score 38. Higher scores mean better outcome in cognitive functions. [Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

8. Communicative Effectiveness Index (CETI)
Minimum score 0, maximum score 100. Higher scores mean better outcome in communicative effectiveness. [Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

9. General Health Questionnaire 12 questions (GHQ-12)
Minimum score 0, maximum score 36. Lower scores mean mean better outcome in general health. [Time Frame: Changes from baseline scores at 6 and 16 (+-2) weeks.]

10. ELIGIBILITY

Sex/Gender:

Sex: All

Gender Based: No

Minimum Age: 18

Unit of time: Years

Maximum Age: No limit

Unit of time: Years

Accepts Healthy Volunteers: No

Eligibility Criteria:

Inclusion Criteria:

- Aphasia 3 months post stroke diagnosed by SLP
- Apraxia of Speech 3 months post stroke diagnosed by SLP
- Being able to participate in rehabilitation in Swedish (not in need of translator to take part in treatment).

Exclusion Criteria:

- Advanced cognitive decline
- Severe visual impairment
- Severe hearing-impairment

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, Associate professor, SLP

Official's Role: Study Principal Investigator

Facility information:

Facility name: Karolinska Institutet, CLINTEC, Division of Speech and Language Pathology, F67, Karolinska University Hospital, Huddinge

City: Stockholm

ZIP/Postal Code: 141 86

Individual Site Status: Recruiting

Facility Contact:

Name: Marika Schütz

Degree: Doctoral student

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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

Statistical Analysis Plan (SAP)

Informed Consent Form (ICF)

Time Frame: 2021-2031

Access Criteria: Swedish National Data Service open source http://snd.gu.se