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

Informed Consent

NCT ID:

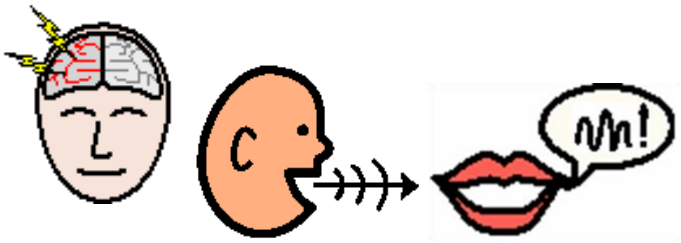
DATE: 2021-06-18

MIRAA - Implementation of Intensive Rehabilitation of Aphasia and/or Apraxia of Speech in Swedish Healthcare

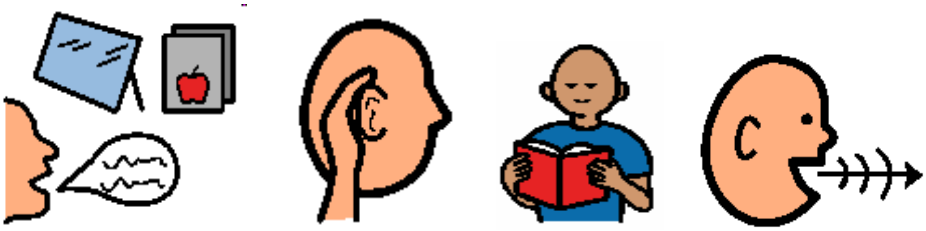
A study on intensive rehabilitation of language and speech after stroke

Information to the research participant

Do you want to participate in research?
Here you get information about the project and what it means to participate.



At **Karolinska Institutet** we are conducting a study on intensive training of language or speech after a stroke.



The purpose of the study is to develop better treatments for people who have problems with their language or speech after a brain injury.

If you participate in the study, you agree that we use your test results in research. The principal researcher for the project is Karolinska Institutet.

If you agree to be included in the study, your rehabilitation will consist of approximately 60 hours of speech therapy training for six weeks. The training is set up individually according to your goals.

You are randomized to either start training immediately or to start training after six weeks (control group). If you have to wait six weeks, you will not receive speech therapy during this period.

Testing of language, speech and quality of life takes place on three occasions, directly at the beginning and end of the training period with follow-up after about four months.

Your next of kin answers questions about quality of life and communication.

6 weeks

16 weeks

1:th test

2:and test and interview/questionnaire

3:rd test

A	Intervention period, 6 weeks	None or less intensive rehab 16 (+-2) weeks	
B	Control, 6 weeks Waiting period	Intervention period, 6 weeks	None or less intensive rehab 16 (+-2) weeks

If you are randomized to the control group, testing takes place on four occasions.

6 weeks

6 weeks

16 weeks

1:th test

2:and test

3:rd test and interview/questionnaire

4:th test

After intervention you assess how satisfied you are with the intensive training.

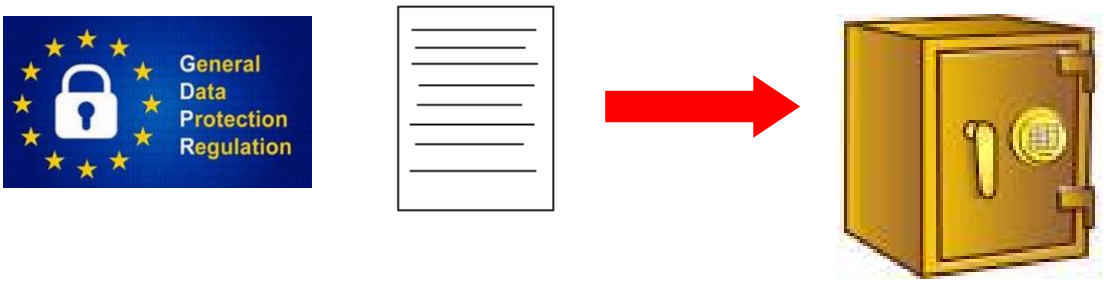
Possible consequences and risks with participating in the study
It is not considered to involve any medical risk to participate in the study, however, you may get tired from the intensive training.

Repeated testing can also be tiring.

Benefits with the study?
The benefit of the study is that it can lead to your speech and / or language and communication getting better. You help to develop better rehabilitation methods for people with aphasia and speech impairment.

What happens to the data?
The project will collect and register information about you. Your answers and your results will be handled so that unauthorized persons cannot have access to them.

Karolinska Institutet saves your test results, but without your name. We also save information about your age, sex, diagnosis and where in the brain your injury has affected you.



The material is coded and can't be connected to you. All personal data is protected by confidentiality and the EU Data Protection Act (GDPR).

How do I get information about the results of the study?

Your speech language pathologist will give you information about your test results. Results from the entire study will be published in scientific journals and in the journal Afasi.

Insurance and compensation

Your regular patient insurance is valid as protection when you get intervention in this study.
You **do not receive any compensation** for participating in the study.

Participation is voluntary

- It is **voluntary** to participate in the study. You **can end your participation** at any time without affecting your continued rehabilitation.
- According to the EU Data Protection Act (**GDPR**), you have the **right to access information** about you, and have it **revised, corrected** or **deleted**.

Principal researcher / contact person:
Ellika Schalling, Associate Professor, Speech Language Pathologist, Division of Speech and Language Pathology, Department of Clinical Science, Intervention and Technology, Karolinska Institutet,
tel: 08-5248 8912, e-mail: ellika.schalling@ki.se

Participating researcher and responsible for conducting assessments:
Marika Schütz, Speech Language Pathologist, doctoral student at Karolinska Institutet. Phone: 0737570430, e-mail: marika.schutz@ki.se

Consent to participate in the study – research person

I have received oral, image-supported and written information about the study and have had the opportunity to ask questions. I can keep the written image-supported information.

☐  **YES** I want to be part of this study

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☐  **Yes** I agree that information about me is processed in the manner described

Place and date	Signature
	Name clarification

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Information to research person's next of kin

At Karolinska Institutet, a study is conducted on intensive training of language and speech after a stroke. The purpose of the study is to create better treatments for people who have problems with the speech or language after brain injury. If your next of kin has agreed to participate in the study, the rehabilitation will consist of approximately 60 hours of speech-language pathology intervention for six weeks. The training is set up individually according to the person's goals. The participants are randomized to either start training immediately or to start training after six weeks (control group). The participants in the control group do not receive speech-language pathology intervention during the waiting period. Testing of language, speech and quality of life takes place on three occasions, directly at the beginning and end of the training period with follow-up after about four months. If your next of kin is randomized to the control group, testing takes place on four occasions. During the testing, we will ask you as next to kin to answer questions about quality of life and communication. You will complete two different questionnaires at each test point.

A	Intervention period, 6 weeks	None or less intensive rehab 16 (+-2) weeks	
B	Control, 6 weeks Waiting period	Intervention period, 6 weeks	None or less intensive rehab 16 (+-2) weeks

Information is obtained about the participants' sex, age, level of education, time since illness, aphasia type and possible speech impairment to provide more knowledge about which people with aphasia and / or speech impairment can participate in intensive rehabilitation. A small group of participants also participate in in-depth interviews and focus groups. Information collected will be pseudonymized. This means that when the information is processed, names or other personal information will not appear. Information is treated confidentially and with respect to confidentiality (pseudonymization is guaranteed).

According to the EU Data Protection Regulation GDPR, Karolinska Institutet (KI) is responsible for the processing of the researchers' personal data and the other data handled in this study. There is strong confidentiality for information about health and other personal matters. According to the EU Data Protection Regulation, particpants have the right to access the personal data handled in the study free of charge, and if necessary to have any errors corrected. Participants may also request that data on them be deleted and that the processing of personal data be restricted. To take part of the information, contact Ellika Schalling, e-mail: ellika.schalling@ki.se or telephone: 08-5248 8912. Contact information for KI's data protection representative is: Mats Gustavsson, email: mats.gustavsson@ki.se or telephone: 08-52486473. If the participants are dissatisfied with how personal data is processed, they have the right to submit a complaint to the Data Inspectorate, which is the supervisory authority. After 10 years, the code key will be destroyed. After that, it is no longer possible to request an extract from the register.

Responsible for the research
Responsible for the research and personal data controller is Karolinska Institutet.
If you have questions about how the information is processed, you can contact:
KI's data protection representative (dataskyddsombud@ki.se) or

Principal researcher / contact person:
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Participating researcher and responsible for conducting assessments:
Marika Schütz, Speech Language Pathologist, doctoral student at Karolinska Institutet. Phone: 0737570430, e-mail: marika.schutz@ki.se

Consent to participate in the study – next of kin research person

I have received oral and written information about the study and have had the opportunity to ask questions. I can keep the written information.

☐  **YES** I want to be part of this study

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INFORMATION TO PARTICIPATING SLPs

At Karolinska Institutet, a study is conducted on intensive training of aphasia and apraxia of speech after stroke. In the MIRAA study (Multimodal Intensive Rehabilitation of Aphasia and Speech Apraxia), speech language pathologists across the country that conduct speech-language rehabilitation post stroke are invited to participate. The purpose is primarily to study the extent to which people with aphasia and / or speech impairment can participate in intensive care and identify factors that prevent or facilitate this. The study also aims to compare the effects of intensive intervention regarding language, speech, communication and quality of life with a control group. The project is expected to be of great importance for the rehabilitation of language and speech after stroke by creating opportunities for clinically active speech-language pathologists (SLPs) to be informed about updated methods for intensive rehabilitation, promote access to evidence-based aphasia rehabilitation, and promote the introduction of the National Board of Health and Welfare's new guidelines by detecting factors that facilitate or complicate intensive implementation.

Who can participate in the study?
Speech language pathologists who work with rehabilitation of people with aphasia and / or speech impairment after stroke, in rehabilitation and speech-language pathology clinics across the country can participate in the study. We are looking for both clinics that currently conduct intensive rehabilitation and those that have not yet implemented this approach. Estimated start of the projects is in the spring of 2021.

Which patients can be included in the study?
The SLPs recruit participants from the regular waiting list and from patients on their current case load for intensive training. Participants have to be able to participate in rehabilitation at the same clinic throughout the intervention period. People with persistent aphasia and / or speech impairment from ages 18 and up are recruited in the subacute and chronic phases, i. e. at least 3 months after the person had his stroke. There is no upper age limit to participating in the study as it has been seen that people can improve many years after a stroke. Participants must have Swedish as a functioning language in everyday life, "functional Swedish" in the study, people who need an interpreter for rehabilitation of language and speech are not included. The recruiting SLPs assesses whether the participant has the opportunity to participate in rehabilitation in Swedish. In other respects, a native language other than Swedish is no limitation An exclusion criteria is if cognitive impairment is expected to hinder participation in the rehabilitation of language and speech. People with severe visual impairment and / or hearing can also not be included in the study.

What does participation in the study mean?
In January 2021, SLPs participating in the study will be offered an introductory free 2-day workshop in Stockholm with in-depth study of several different methods for individual rehabilitation of aphasia (VNeST, SFA, MODAK and ELA) and in groups (ILAT, M-MAT) and for apraxia of speech (SPT, CAAST, Scripts), training according to ICAP program (Intensive Comprehensive Aphasia Program) and practical arrangements for intervention according to MIRAA. The program also includes working with goals, motivation creation, information for participants and next of kin. Additional training and knowledge exchange

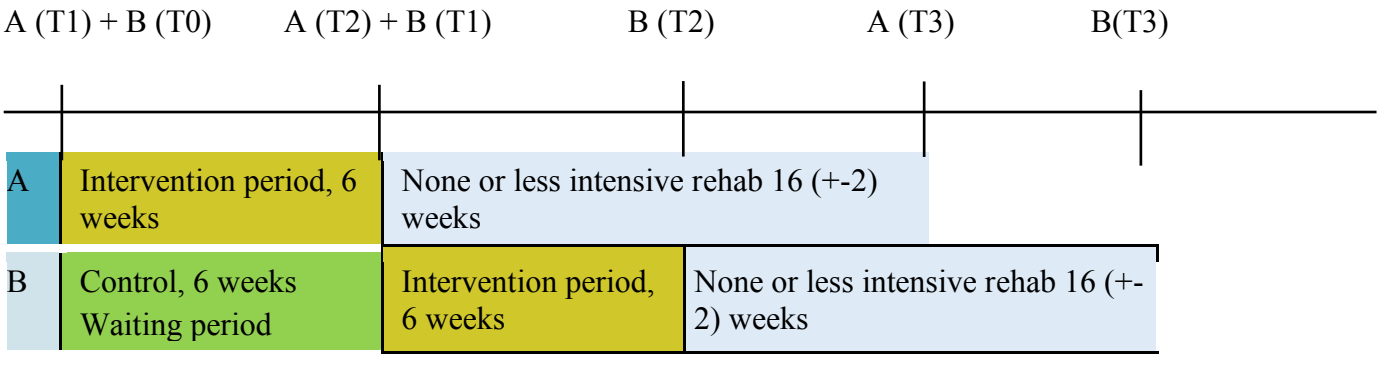
takes place digitally during the workshops/lectures. Workshops and lectures are free of charge, any costs in connection with workshops in the form of leave from work, travel and accommodation are not paid for. To be able to participate in the study, you must participate in the introductory workshop.

Intervention

Participating SLPs carry out one (or more) period (s) of intensive speech and language intervention according to MIRAA during 2021-2022. The intervention method is an M-ICAP (Modified Intensive Comprehensive Aphasia Program), characteristic of an ICAP program is that it is intensive, consists of rehabilitation in several different modalities (comprehensive) to promote rehabilitation of communication both individually and in groups. The program is supplemented by digital training and homework to provide increased intensity. In an ICAP, the therapist has an ICF focus, i. e. rehabilitation is focused on both functional improvement and increased activity and participation. Participating SLPs receive further training in commonly used evidence-based training methods for aphasia and apraxia of speech used in an ICAP. An ICAP creates unique rehabilitation programs consisting of different methods to best meet patients' individual needs. The SLPs keep a logbook of what methods they have used and to what extent this has happened. Briefly, an ICAP can be described as a multimodal intensive rehabilitation program for people with aphasia that was created to meet the complexity of the individual's need for rehabilitation in the event of extensive communication difficulties. MIRAA is a modified variant of ICAP as the rehabilitation also includes speech practice which often coexists with aphasia, and intensity is slightly lower (two instead of three hours per day). The target level for training with MIRAA is 60 hours of rehabilitation over six weeks. The training is set up individually according to the person's goals and the clinics' possibilities.

Randomization and testing

Participants who meet the inclusion criteria are recruited consecutively from the clinics' waiting list and among the patients on the SLPs' current case load. The goal is to recruit at least 2 to 3 participants per intervention wave. The participating SLPs are randomized into two groups, half are control groups and have to wait six weeks before they give treatment and the other half give treatment immediately. The participants with aphasia/apraxia of speech who are randomized to the control group have to wait six weeks for intervention.



Language testing (with external test person) is performed at start (T1) and end of intervention (T2) with follow-up after 16 weeks (T3). In the control group, further testing is performed six weeks before the start of intervention (T0). In some cases, this testing is done by a participating SLP or a colleague who then receives an introduction and review of the test battery. Any participating next of kin answer questions about quality of life and communication.

Demographic information is obtained about sex, age, time since illness, possible brain fatigue and aphasia type to provide more knowledge about which people with aphasia can participate in intensive rehabilitation. SLPs and patients will be asked how they perceived the treatment in terms of satisfaction, content and intensity. A small group of SLPs and researchers also participate in in-depth interviews, clinic observation and focus group interviews.

Information collected will be pseudonymized. This means that when the information is processed, names or other personal information will not appear. Information is treated confidentially and with respect to confidentiality (pseudonymization is guaranteed). Data collected through tests and other information obtained is compiled, all information is pseudonymised before analysis, i.e., the information is not kept together with contact information. Consent forms, compilation of data and films and a code key will be stored in a locked file cabinet at the Division of Speech and Language Pathology, Karolinska Institutet. Archiving time ten years. Only people involved in the study have access to the material. According to the EU Data Protection Regulation GDPR, Karolinska Institutet (KI) is responsible for the processing of the researchers' personal data and the other data handled in this study. There is strong confidentiality for information about health and other personal matters. According to the EU Data Protection Regulation, participants have the right to access the personal data handled in the study free of charge, and if necessary to have any errors corrected. Participants may also request that data about them be deleted and that the handling of personal data be restricted. To take part of the information, contact Ellika Schalling, e-mail: ellika.schalling@ki.se or telephone: 08-5248 8912. Contact information for KI's data protection representative is: Mats Gustavsson, email: mats.gustavsson@ki.se or telephone : 08-52486473. If participants are dissatisfied with how personal data is handled, they have the right to submit a complaint to the Data Inspectorate, which is the supervisory authority. After 10 years, the code key will be destroyed. After that, it is no longer possible to request an extract from the register.

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Consent to participate in the study - speech pathologist

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☐ I agree to participate in the study MIRAA - A national study regarding intensive rehabilitation of aphasia and speech practice after stroke

☐ I agree that information about me is processed in the manner described in the research person's information.

Place and date	Signature speech language patologist
	Name clarification