

Trial Description

Title

Efficacy of a Strategy-Based Intervention on Text Level Reading Comprehension in Persons with Aphasia: A Waiting Phase Controlled Pre-Post Study

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Acquired brain injury as caused by stroke can result in a variety of language difficulties including aphasia. With aphasia, it may be difficult to understand texts such as letters, e-mails or books. Current research does not allow sound conclusions about the effectivity of different treatments by speech and language pathologists. However, there are indications that specific reading strategies may help to improve text comprehension.

In this study, the effects of a waiting period and of two different combinations of reading strategy interventions will be compared. 24 adults with aphasia will participate in a waiting period without aphasia therapy and in 14 treatment sessions. Each session lasts one hour. Seven of these sessions will focus on the comprehension of details and the remainder on the text's main information. Participants must have had (residual) aphasia for at least three months, be at least 18 years old, speak German as their native language and have problems with reading and understanding texts. Participation is not open to those experiencing reading difficulties prior to the onset of aphasia or with any disease that results in decreasing or fluctuating language or cognition. Before and after each treatment period, text comprehension and reading activities will be examined. We will investigate whether therapy will result in larger improvements than no therapy, and whether there will be strategy-specific effects on reading comprehension. We expect that strategy-based interventions will cause stronger improvements than no therapy and that there will be strategy-specific effects on different text comprehension processes. Furthermore, we expect that participants' everyday reading activities will improve following the interventions.

Brief Summary in Scientific Language

Introduction

At least 68% of persons with aphasia (PWA) experience reading difficulties. These functional restrictions affect the quality of life and important domains of participation. Strategy-based interventions are promising treatment approaches especially for persons with mild to moderate aphasia. However, empirical evidence for the efficacy of strategy-based interventions to treat text level reading comprehension deficits in PWA remains rare. Hence, the primary objective of this study is the analysis of the efficacy of a strategy-based intervention on text level reading comprehension and on activities related to reading in PWA. Furthermore, relations between specific cognitive functions and reading comprehension

measures as well as treatment outcome will be investigated.

Methods and analysis

In a waiting phase controlled pre-post trial, 24 persons with mild to moderate aphasia associated with text comprehension difficulties will participate first in a waiting period and then in a strategy-based intervention. The intervention period will consist of 14 face-to-face-sessions, 60 minutes each, plus at least 60 minutes homework after each session. Based on cognitive theories of reading, we will apply two combinations of strategies designed to specifically improve the comprehension of either the micro- or the macrostructure, respectively. To explore strategy-specific effects, participants will be randomly allocated to two parallel groups that will receive these combinations in seven sessions each, in interchanged order. Assessments will be implemented before and after each period as well as two follow-ups after three and six months. Participants will be blinded regarding the specific hypotheses of the study. However, neither participants nor therapists can be blinded regarding the strategies they will use during treatment. The primary outcome measure is text level reading comprehension represented by the score TCT-D Total measured with a German version of Test de Compréhension de Textes. Secondary outcome measures address specific reading functions, activities and attitudes related to reading, and cognitive functions. The sample size was determined with an a priori power analysis. For statistical analysis, we will use contrast analyses within repeated-measures ANOVA models. We expect significant improvements in primary and secondary outcome measures during the intervention as compared to changes during the waiting period.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Anonymized participant-level datasets and statistical codes will be provided on OSF repository after journal publication according to FAIR principles (findable, accessible, interoperable and re-usable) with a Digital Object Identifiers (DOI) and a CC-BY Creative Commons Licence.

Organizational Data

- DRKS-ID: **DRKS00021411**
- Date of Registration in DRKS: **2020/11/17**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **20-10074-KA-MunmErw+Ko , Ethikkommission des Deutschen Bundesverbandes der akademischen Sprachtherapeuten (dbs)**

Secondary IDs

Health condition or Problem studied

- ICD10: **R47.0 - Dysphasia and aphasia**
- ICD10: **R48.0 - Dyslexia and alexia**

Interventions/Observational Groups

- Arm 1: **24 persons with aphasia will be allocated to two groups with the ratio 1:1 by stratified permuted block randomization. We will stratify for age, severity of aphasia and the score TCT-D Total. After the waiting period, we will apply two combinations of strategies designed to specifically improve the comprehension of either the micro- or the macrostructure, respectively. To explore strategy-specific effects, participants will be randomly allocated to two parallel groups that will receive these combinations in seven sessions each, in interchanged order.**

Arm 1: Strategy-based intervention to target the comprehension of the macrostructure: stimulus material: articles from magazines; strategies: 1. mind-map based on advance organizers, 2. constrained summarization; 7 x 60minutes, twice a week, in individual therapy, plus 7 x 60minutes homework

- Arm 2: **Strategy-based intervention to target the comprehension of the microstructure: stimulus material: articles from magazines; strategies: 1. developing questions and answers about micropropositions, 2. elaboration of the text by semantically coherent replacement of micropropositions; 7 x 60minutes, twice a week, in individual therapy, plus 7 x 60minutes homework**
- Arm 3: **waiting period: 4 weeks, no aphasia therapy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Outcome name and method of measurement: TCT-D Total: TCT-D Total is the sum

**of microstructure and macrostructure across all subtests of the German version of Test de Compréhension de Textes (TCT);
timepoints: 6 assessments: before, between and after the periods (waiting period, strategy-based intervention to target the comprehension of the macrostructure, strategy-based intervention to target the comprehension of the microstructure) and 3 and 6 months as follow-up**

Secondary Outcome

- Outcome names and methods of measurement: microstructure, macrostructure, situational model and reading time measured with the German version of Test de Compréhension de Textes (TCT); reading activities measured with the German version of Comprehensive Assessment of Reading in Aphasia (CARA) reading questionnaire; timepoints: 6 assessments: before, between and after the periods (waiting period, strategy-based intervention to target the comprehension of the macrostructure, strategy-based intervention to target the comprehension of the microstructure) and 3 and 6 months as follow-up

- Outcome names and methods of measurement: inferences and text reception with MAKRO-Screening; cognitive functions with subtests from WMS-R, WMS-IV and ACL; timepoints: 2 assessments: before and after the strategy-based interventions

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **München**
- Doctor's Practice **Erfurt**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/12/01**
- Target Sample Size: **24**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- **Age of at least 18 years**
- **aphasia according to Aachener Aphasia Test (AAT) OR no current symptoms / only residual aphasia according to the latest AAT assessment but previously diagnosed aphasia and current language difficulties (subjective or perceived by a SLP)**
- **anomalous scores in the German version of Test de Compréhension de Textes (TCT-D)**
- **native language: German**
- **at least 3 months post-onset**

Exclusion criteria

- **global aphasia AND / OR severe problems in word level reading (score < 12 in AAT subtest “single word reading comprehension”) AND / OR severe problems in written language (score < 22 in category “written language” in AAT)**
- **neurological, psychiatric or any other disease that impedes a (repeated) assessment and valid interpretation with the AAT or TCT-D (particularly if the disease can result in decreasing or strongly fluctuating linguistic or cognitive performance)**
- **pre-morbid dyslexia**

Addresses

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.