Trial Description

Title

The relationship between distress and language in aphasia

Trial Acronym

APHA_STRESS

URL of the trial

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Brief Summary in Lay Language

Brief Summary in Scientific Language

The study 'The relationship between distress and language in aphasia' addresses the impact of subjective and physiological distress on language processes in people with aphasia. Furthermore, this impact is to be investigated in terms of its variability in a longitudinal design. This study aims for a better understanding of the relationship between subjective indicators of distress (measured with questionnaires), physiological indicators of distress (measured with heart rate variability) and illness-related impairments of language. Furthermore, within the scope of this study, we will develop a relaxation therapy which is suitable for people with aphasia. Thereby, we want to make a practical contribution to the clinical treatment of people with aphasia. At present, the relationship between distress and language in these patients has not been investigated deeply. Furthermore, there is a lack of interventions which are on the one hand suitable for people with aphasia and which on the other hand are scientifically valid. This study addresses these problems using an experimental interventional design.

We will address the following research questions: Do subjective and physiological indicators of distress have an impact on language processes in people with aphasia? Can this relationship be altered by speech therapy and relaxation therapy?

In the first phase of this project we aim to investigate the relationship between distress and language in people with aphasia using an experimental design. In the second phase of this project we take a closer look at the variability of this relationship during a period of intensive speech and language therapy. In this second phase an adapted version of progressive muscle relaxation therapy will be applied. It will be administered in a two-week long group therapy. Furthermore, we will investigate chronic distress experiences, depression, anxiety, and quality of life.

We expect that speech processes (production and perception) are influenced by cognitive and physiological distress (i.e. the perception of noise). Furthermore, we expect an increase of language-related distress itself when priming is

administered with cognitive and physiological distress. In contrast, we expect a decrease of language-related distress when a relaxation intervention is presented before a language task. Thus, language parameters (production and perception) are expected to be indirectly improved by a relaxation intervention.

After confirmation of these relationships, as a conclusion, the intensive speech and language therapy (treatment as usual) will be complemented by an adapted relaxation therapy in a group setting. As the intervention developed in this study is characterised as being very little dependent on language, applications in other settings (e.g. therapy of traumatised refugees) are also possible.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00015470**
- Date of Registration in DRKS: **2018/10/01**
- 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.: **EK 138-18 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

Health condition or Problem studied

- ICD10: **R47.0 - Dysphasia and aphasia**

Interventions/Observational Groups

- Arm 1: **Phase 1: N=30, one-armed, within-subject design. Impact of stressors (cognitive and physiological) on language-related distress and language parameters. Cross-sectional design, 3 measurements (Baseline, speech production, speech reception)**
- Arm 2: **Phase 2: N=30, crossover design, interventional. Relaxation therapy group followed by control group (general nonverbal group therapy).**

Measurements before, between and after groups (similar to Phase 1)

- Arm 3: **Phase 2: N=30 crossover design, interventional Control group (general nonverbal group therapy) followed by relaxation therapy group. Measurements before, between and after groups (similar to Phase 1)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Crossover**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1. Physiological distress: heart rate variability, measured by lead of heart rate during independent variables (progressive muscle relaxation, cognitive distress, physiological distress [noise]) and dependent variables (speech production, speech perception)

2. Subjective distress: measured by changes in valence and arousal ratings (nonverbal SAM-scales) before and after IVs and DVs

Measurements in Phase 1: on three consecutive time points (cross-sectional design). Measurements in Phase 2: on three consecutive time points before after and in between group therapies (3 times 3 measurements, 7 weeks, longitudinal design)

3. Chronic distress and related parameters: questionnaires
- Depression and anxiety: Hospital Anxiety Depression Scale (HADS), Beck's Depressionsinventory (BDI-II)
- Quality of life: the Aachen inventory of quality of life (ALQI)
- Distress: Stress coping inventory (SCI), Perceived Stress Questionnaire (PSQ-20)

Measurements in Phase 1: on the first three consecutive time points.
Measurements in Phase 2: in the first session of each measurement block: before after and in between group therapies

Secondary Outcome

Speech processes in 1. Speech production (analysis of spontaneous speech, linguistic parameters) and 2. Speech perception (analysis of auditive speech perception)

Measurements in Phase 1: on three consecutive time points (cross-sectional design). Measurements in Phase 2: on three consecutive time points before after and in between group therapies (3 times 3 measurements, 7 weeks, longitudinal design)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurologie, Aachen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/10/15**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

1. Age >18
2. Informed consent
3. Diagnosed with aphasia (post-acute phase: 2-12 months post stroke/trauma or chronic phase: >12 months post stroke/trauma)
4. Situative appropriate speech perception (AAT subtest speech perception: PR > 10 or positive appraisal of speech and language therapist
5. Inward patients (specialised ward for aphasia, University Clinics Aachen)

Exclusion criteria

1. Non-compensability of visual impairments (e.g. neglect, hemianopsia)
2. Motoric or sensoric impariments on the left side of the body (in left-hemispheric stroke)

3. Psychotic, obsessive-compulsory or hypochondric disorder
4. Restrictive impairments of auditory processing; high auditive sensitivity

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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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 planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Prüfplan Studie APHA_STRESS**

** 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.*